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HAZARDS IN REUSE OF DISPOSABLE DIALYSIS DEVICES—APPENDIX

STAFF REPORT

TO THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

DECEMBER 1986

Serial No. 99-N

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APPENDIX V

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FRIDAY, AUGUST 22, 1986

Washington, DC.

Proceedings in the matter of the deposition of: John E. Marshall, Ph.D., held in the offices of the U.S. Senate Special Committee on Aging, SD-G31, Dirksen Senate Office Building, Washington, DC 20510, before Ray Boyum, notary public in and for the District of Columbia, when were present on behalf of the parties:

For the U.S. Senate Committee on Aging: James Michie, chief investigator; David G. Schulke, investigator.

For the deponent Dr. John E. Marshall: Richard J. Riseberg, chief counsel, Public Health Service, Washington, DC.

Also present: Morgan J. Frankel, assistant Senate legal counsel, U.S. Senate, Washington, DC.

Mr. **Michie**. We are on the record now.

My name is James Michie, I am chief investigator for the Special Committee on Aging of the U.S. Senate.

Present with me here in room SD-G31 of the Dirksen Senate Office Building is committee investigator, David Schulke; the notary public and stenographer, Ray Boyum; Morgan J. Frankel of the Senate Legal Counsel; and the deponent, Dr. John E. Marshall, Director of the National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service.

Dr. Marshall is accompanied by legal counsel, Richard Riseberg, counsel to the Public Health Service.

On August 18, Dr. Marshall was served with a subpoena and notice of deposition authorized by Senator John H. Heinz, chairman of the Special Committee on Aging, for the purpose of being deposed by committee staff on August 27, 1986.

Due to Dr. Marshall's vacation schedule, he has agreed to undergo deposition on this 22d day of August 1986. A prepared letter was submitted by him to Senator Heinz stating so, and we will make that letter a part of the record. Dr. Marshall's letter will be made a part of the deposition record along with a copy of the subpoena and notice of deposition.

Prior to being sworn in, Dr. Marshall, I want to remind you that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury. Are you ready to proceed?

Mr. **Riseberg**. I am counsel for Dr. Marshall.

Mr. **Michie**. We recognize Mr. Riseman——

Mr. **Riseberg**. Riseberg.

Mr. **Michie**. Excuse me. Mr. Riseberg.

Mr. **Riseberg**. For the record, I am Richard J. Riseberg, chief counsel to the Public Health Service. I have been designated by Dr. Marshall and the department to accompany Dr. Marshall to this interview.

Dr. Marshall has asked me to indicate again for the record that he is here voluntarily in order to cooperate with the Senate Special Committee on Aging in connection with its study of issues related to dialyzer reuse and is participating in today's interview solely on that basis.

He has been advised by attorneys for the Department that the subpoena received recently served upon him is of doubtful legality and he, therefore, does not regard his participation to be compelled by the subpoena or governed by its terms.

Nevertheless, subject to that understanding, he looks forward to answering any questions that you may have.

Mr. **Michie**. Would the notary public administer the oath to Dr. Marshall.

Dr. **Marshall**. I am not prepared to be sworn.

Mr. **Michie**. For the record, Dr. Marshall, are you refusing to be sworn for this deposition under subpoena?

Dr. **Marshall**. Are you——

Mr. **Michie**. Dr. Marshall, would you speak up, please?

Dr. **Marshall**. I wish to confer with my counsel before I answer.

Mr. **Michie**. Please.

[Reporter's note.—Witness confers with his counsel.]

Dr. **Marshall**. No.

Mr. **Michie**. Pardon?

Dr. **Marshall**. No.

Mr. **Michie**. Are you not refusing to take the oath?

Dr. **Marshall**. I am refusing to take the oath.

Mr. **Riseberg**. Dr. Marshall's reason is that he is here simply to cooperate with the committee. He is not here under compulsion and while he is naturally prepared to answer the questions truthfully to the best of his knowledge, that he is not prepared to be sworn in accordance with any kind of formal proceeding.

Mr. **Frankel**. This is Morgan Frankel, I am assistant Senate legal counsel.

Dr. Marshall, did you receive a subpoena signed by the chairman, Senator Heinz, chairman of the Aging Committee?

Dr. **Marshall**. I did.

Mr. **Frankel**. Did you receive a notice of Senate deposition also signed by the chairman?

Dr. **Marshall**. I did.

Mr. **Frankel**. With those did you receive a copy of the committee's rules of procedure?

Dr. **Marshall**. I did.

Mr. **Frankel**. Are yoiu familiar with or have you had an opportunity to review rule 6.3 which provides "witnesses shall be examined upon oath administered by an individual authorized by local law to administer oaths?"

Dr. **Marshall**. I don't recall being familiar but now that you have read it to me, I suppose I can say—but if I can look at it?

Mr. **Frankel**. I will share it with you so you can satisfy yourself that that is in the rules.

Dr. **Marshall**. You say this is in——

Mr. **Frankel**. 6.3.

Dr. **Marshall**. 6.3.

Mr. **Riseberg**. Would you like me to respond?

Dr. **Marshall**. Sure.

Mr. **Riseberg**. As——

Mr. **Michie**. Let the record show that counsel for the deponent has just read the material provided by Mr. Frankel.

Please go ahead.

Mr. **Riseberg**. As I have indicated to you previously, after reviewing that rule in the context of applicable law, it is our advice to Dr. Marshall that we have questions about the legality of the subpoena and that in the context of this proceeding we don't think it is—don't think he can be validly—that he was validly subpoenaed here, and we certainly would not be prepared to proceed on that basis.

Mr. **Frankel**. Dr. Marshall, I would like to refer you to the Committee System Reorganization Amendments of 1977, known as Senate Resolution 4, and which established the Special Committee on Aging, and provides under subsection C(1) that the special committee is authorized in its discretion to require by subpoena or otherwise the attendance of witnesses and production of correspondence, books, papers, and documents—that was paragraph F; paragraph G, to take depositions and other testimony.

Do you understand those provisions as I have described them?

Dr. **Marshall**. Well, I can read them and I have heard what you said, yes.

Mr. **Frankel**. I would also like to refer you to title 2, United States Code, section 192 which provides for criminal penalties for a witness who, having been summoned by the authority of either House of Congress to give testimony or by any committee of one of the Houses, whose refusal to testify shall lead to the possibility of criminal sanctions.

Are you aware of that?

Dr. **Marshall**. I am aware of it.

Mr. **Frankel**. It's time to administer the oath.

Mr. **Michie**. Again I would ask the stenographer and notary public to administer the oath to Dr. Marshall.

Dr. **Marshall**. I am not prepared to take an oath.

Mr. **Michie**. So it is a matter of record that Dr. Marshall—correct me if I am wrong—that you are declining to honor the subpoena, the notice of deposition, as well as declining to be sworn for deposition. Is that correct?

Dr. **Marshall**. That's correct.

Mr. **Michie**. This will be referred to the chairman of this committee for disposition, that being your refusal to cooperate and to honor the subpoena as well as the notice of disposition, and your refusal to be sworn in for testimony.

Dr. **Marshall**. I think the record should not reflect that I refused to cooperate. I haven't refused to cooperate. I have just not accepted this subpoena as a valid subpoena; and I have not accepted the direction that I be sworn.

Mr. **Michie**. That is understood.

This deposition is now recessed until further notice.

[Whereupon, at 2:56 p.m., the deposition proceedings in this matter were recessed.]

UNITED STATES OF AMERICA

Congress of the United States

To John E. Marshall, Ph.D., Director, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service, U.S. Department of Health and Human Services, Rockville, Maryland, **Greeting:**

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* August 27, *19*86, *at* two *o'clock* p.*m., at their committee room* SD-G33 in the Dirksen Senate Office Building, *then and there to testify what you may know relative to the subject matters under consideration by said committee,* in sworn deposition to be conducted by committee staff.

Hereof fail not, *as you will answer your default under the pains and penalties in such cases made and provided.*

To James F. Michie, Chief Investigator, *to serve and return.*

Given *under my hand, by order of the committee, this* 14th *day of* August, *in the year of our Lord one thousand nine hundred and* eighty-six

John Heinz

Chairman, Committee on Aging

UNITED STATES OF AMERICA

Congress of the United States

Notice of
Senate Deposition

To John E. Marshall, Ph.D., Director, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service, U.S. Department of Health and Human Services, Rockville, Maryland , **Greeting:**

Please *take notice that at* two *o'clock* p.m., *on* August 27 , *19* 86 , at Rm. SD-G33, Dirksen Senate Office Bldg., Washington, D.C., ~~at~~ J.F. Michie, D.G. Schulke & C.C. Jennings , *of the staff of the* Special committee *on* Aging *of the Senate of the United States, will take your deposition on oral examination concerning what you may know relative to the subject matters under consideration by said* Special *committee. The deposition will be taken before a notary public, or before some other officer authorized by local law to administer oaths; it will be taken pursuant to the* Special *committee's rules, a copy of which are attached.*

Given *under my hand, by authority vested in me by the* Special *committee, on* August 14 ,
19 86 .

John Heinz
JOHN HEINZ
Chairman

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

National Center for Health Services Research
and Health Care Technology Assessment
Rockville MD 20857

August 14, 1986

The Honorable John Heinz
Chairman
Special Committee on Aging
Washington, D.C. 20510

Dear Senator Heinz:

While I appreciate having the opportunity to appear before the staff of the Special Subcommittee on Aging to make a deposition upon oral examination concerning what I may know relative to subject matters under consideration by the Special Committee, I am scheduled to be out of town on August 27. This is to request an alternate date and time.

Based on discussion with James F. Michie, Chief Investigator, we have ascertained that 2:00 p.m. on Friday, August 22, would be a suitable alternate date and time. I would appreciate your favorable consideration and approval of my request.

Sincerely,

J E Marshall

John E. Marshall
Director

TUESDAY, AUGUST 26, 1986

Washington, DC.

Deposition of Martin N. Erlichman, called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 9:05 a.m., before Albert R. Sparks, a notary public in and for the District of Columbia.

Present:

For the Special Committee on Aging:

James F. Michie, chief investigator, U.S. Senate, Special Committee on Aging, room SDG-33, Dirksen Senate Office Building, Washington, DC 20510 (202) 224-5364.

David Schulke, Committee Investigator.

Christopher Jennings, committee staff member.

Morgan Frankel, Esq., Office of the Senate Legal Counsel.

For the U.S. Public Health Service:

Richard J. Riseberg, Esq., chief counsel, Public Health Service, room 4-A-53, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 (301) 443-2644.

Mr. MICHIE. We are on the record. Good morning.

My name is James F. Michie. I am chief investigator for the Special Committee on Aging, U.S. Senate. Present with me here in room SDG-31 of the Dirksen Senate Office Building is Committee Investigator David Schulke, Committee Staff Member Christopher Jennings, Morgan Frankel of the Senate Legal Counsel's Office, the notary public and stenographer, Albert R. Sparks, and Martin N. Erlichman, Health Science Analyst, Office of Health Technology Assessment, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service. Mr. Erlichman is accompanied by Richard Riseberg of the Public Health Service general counsel's office.

On August 15, Mr. Erlichman was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging, for the purpose of being deposed by committee staff on this 26th day of August 1986.

A copy of the subpoena and notice of deposition will be made a part of this deposition record.

Prior to being sworn in, Mr. Erlichman, I want to remind you that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury. Are you ready to proceed?

Mr. RISEBERG. I would like to make a statement for the record.

Mr. MICHIE. We'll recognize Mr. Riseberg from the Public Health Service Counsel's Office. Mr. Riseberg.

Mr. RISEBERG. For the record, I am Richard J. Riseberg, chief counsel for the Public Health Service.

I have been designated by the Department to accompany Mr. Erlichman to this interveiw.

The Department has asked me to indicate that it is volunteering to make Mr. Martin Erlichman available in order to cooperate with the Senate Special Committee on Aging in connection with its study of issues related to dialyzer reuse, and he is participating in today's interview solely on that basis.

He has been advised by attorneys for the Department that the subpoena recently served upon him is of doubtful legality and that the Department does not regard his participation to be compelled by the subpoena or governed by its terms.

Nevertheless, subject to this understanding, Mr. Erlichman looks forward to answering any questions you may have.

Mr. MICHIE. I think it is essential for the record that we obtain from you, Mr. Erlichman, your understanding of this proceeding and the reasons for your appearance here today.

Are you aware of Senator Heinz' letters of July 23 and August 15, 1986, to Dr. Otis Bowen, Secretary of the Department of Health and Human Services? Are you aware of these letters?

Mr. ERLICHMAN. I might have seen them. I would have to look at them.

Mr. MICHIE. You don't recall?

Mr. ERLICHMAN. There have been a lot of letters.

Mr. RISEBERG. What are the dates?

Mr. MICHIE. The dates are July 23 and August 15.

I would like you to read these letters, take your time, and at the same time as you read them yourself, I will ask Mr. Schulke to read both letters into the record at this time.

Mr. Schulke?

Mr. SCHULKE. The first letter is dated July 23, 1986, on the letterhead of the U.S. Senate, Special Committee on Aging, addressed to the Honorable Otis R. Bowen, Secretary, Department of Health and Human Services.

> Dear Mr. Secretary: As Chairman of the Special Committee on Aging, I am writing to share with you my deep concern and dismay over learning that department officials presented inaccurate and misleading testimony before the Committee at the March 6, 1986 hearing on the reuse of dialysis devices.
>
> I recently learned of a memorandum prepared by John Marshall, Ph.D., Director, National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) for Robert E. Windom, M.D., Assistant Secretary for Health. The memorandum, a copy of which I have enclosed, is based upon the NCHSR/HCTA's "Assessment of Medical Technology: Reuse of Hemodialysis Devices Labeled for Single Use Only" initiated in April 1986, following the Committee's March 6 hearing.
>
> This alarming and shocking memorandum reveals all too clearly a severe breakdown in communications and coordination among the agencies responsible for the safety and well-being of dialysis patients: the National Institutes of Health (NIH); the Food and Drug Administration (FDA); the Health Care Financing Administration (HCFA); and the Centers for Disease Control (CDC). Indeed, as Dr. Marshall observed in his memorandum, these agencies "have had a long but non-productive involvement with [reuse] issues." Moreover, it confirms many of the serious concerns regarding the safety of reuse that were raised in the Committee's staff report as well as in testimony, but denied or dismissed by witnesses representing the Department of Health and Human Services (DHHS). The Marshall memorandum states, however, that the NCHSR/HCTA assessment "uncovered serious omissions and inaccuracies in the testimony."
>
> The memorandum indicates that Dr. Marshall, the Department's principal witness at the March 6 hearing, was himself the victim of misinformation and lack of

information regarding the safety and efficacy of dialysis device reprocessing and reuse. Further, the findings of the NCHSR/HCTA assessment serve as a strong indictment of failure on the part of those who were responsible for providing Dr. Marshall with accurate and complete information in preparation for his testimony.

The Marshall memorandum establishes that much of the information and data previously used to support the "safety" of reuse, such as the NIH report "Multiple Use of Hemodialyzers" (e.g., the Dean report), is unreliable.

I trust now that you can understand and appreciate why I continue to be deeply concerned for the health and safety of this nation's 80,000 dialysis patients, many of whom have falsely and wrongly been misled into believing that there are no risks associated with the reuse of their dialysis devices.

In light of the NCHSR/HCTA assessment findings and the most recent outbreaks of life-threatening bacterial infections in dialysis patients subjected to reuse, I strongly urge you to take immediate action on Dr. Marshall's recommendation:

"The Public Health Service needs to take a clinically and scientifically based stand with respect to this issue. We need to communicate that directly and emphatically to the Health Care Financing Administration, even if that means recognizing that our earlier testimony was flawed."

In addition, and in the interest of adequately protecting dialysis patients from any further threat of harm and injury, I am requesting that you take immediate action on my earlier recommendations: (1) require dialysis clinics to adequately inform their patients of the risks of reuse and prohibit the clinics from coercing and forcing patients to reuse their dialysis devices; (2) withdraw HCFA's proposed regulations that would lower the dialysis reimbursement rate and, consequently, force still more clinics to reprocess and reuse dialysis devices; (3) conduct appropriate and controlled preclinical and clinical testing to determine the safety and efficacy of the reprocessing and reuse of dialysis devices, and (4) direct the FDA to impose its good manufacturing practice regulations on reprocessors of dialysis devices, and to develop uniform safety standards for the reprocessing and reuse of dialysis devices and supplies.

Should you or your staff have any questions regarding this request, please have your staff contact Jim Michie or David Schulke at 224-5364.

Thank you for your cooperation and assistance in this important matter.

Sincerely, signed "John Heinz, Chairman."

There is an enclosure, which was the July 8 memorandum.

Mr. Michie. Mr. Erlichman, do you recall having seen or read this letter prior to your appearance here today?

Mr. Erlichman. I don't believe so. It's possible, but I don't believe I have seen this memo.

Mr. Michie. Do you recall having seen and read the July 8, 1986, memo to Dr. Windom, who is Assistant Secretary for Health, and Dr. John Marshall, your superior, and Director of the National Center for Health Services Research and Health Care Technology Assessment? Do you recall having seen or read that memo?

Mr. Erlichman. I believe so, but can you show it to me?

Mr. Michie. We will take a recess of 2 minutes now so that we may get a copy for you.

Mr. Erlichman. Thank you.

[Recess taken.]

Mr. Michie. We are back on the record. We are now providing Mr. Erlichman with a copy of the July 8, 1986, memo that was addressed to Dr. Windom and generated by Dr. John Marshall, the Director of the National Center for Health Services Research and Health Care Technology Assessment.

For the record, Mr. Erlichman is now examining this particular memo.

Mr. Erlichman. I have read it.

Mr. Michie. All right. Having read this July 8 1986, memo to Dr. Windom from your superior, Dr. Marshall, do you recall now having seen or read this memo?

Mr. **Erlichman**. Yes, sir, I have seen and read this memo. I believe the first time was when you brought it to my attention when you came to our office about a week or so ago on a Thursday, August—do you want——

Mr. **Michie**. I think it was August 14.

Mr. **Erlichman**. That's correct. I heard of this memo. That was the first time I had seen it in the——

Mr. **Michie**. Record of the March 6, 1986, hearing?

Mr. **Erlichman**. That's correct.

Mr. **Michie**. On this particular issue?

Mr. **Erlichman**. That is correct.

Mr. **Michie**. We will identify the July 23, 1986, letter, along with its attachment, the July 8, 1986, memo, as exhibit 1 of this deposition, and both will be made a part of the record.

[Exhibit 1 was marked and included in the record.]

Mr. **Michie**. If Mr. Schulke would now proceed to read the August 15, 1986, letter into the record.

Mr. **Schulke**. On the letterhead of the U.S. Senate Special Committee on Aging, the letter dated August 15, 1986, to the Honorable Otis R. Bowen, M.D., Secretary of Health and Human Services, from Senator John Heinz:

> Dear Mr. Secretary: I am writing to share with you my recent findings concerning a grave injustice that is being done to Medicare's 80,000 dialysis patients who are threatened by recent actions within the Department of Health and Human Services.
>
> The Aging Committee's ongoing investigation into reuse of disposable dialysis devices has revealed the inexplicable and ill-conceived activities within the Public Health Service (PHS) and the Health Care Financing Administration (HCFA). Specifically, I am referring to the abrupt termination on August 6, 1986 of the assessment of reuse procedures by the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA), and HCFA's premature publication on August 15, 1986 of reductions in Medicare's dialysis reimbursement rates, which will become effective on October 1, 1986.
>
> As you know, HCFA relies very heavily upon NCHSR/HCTA's scientific and technological expertise in developing and finalizing its actions regarding administration of health care financing. I must assume that such was the case in HCFA's decision this week to proceed with the dialysis reimbursement rate reductions. Further, I must assume that HCFA relied upon the NCHSR/HCTA's draft assessment report that was submitted to the Assistant Secretary for Health, Robert E. Windom, M.D., on August 6, 1986.
>
> I deeply regret to inform you that the NCHSR/HCTA report is seriously flawed. The report lacks critically pertinent information concerning deaths, serious injuries, extremely poor reprocessing procedures in dialysis clinics and numerous deficiencies in manufacturing practices of firms that market dialysis and reprocessing devices.
>
> The Committee's investigation has determined that the NCHSR/HCTA staff was forced to hastily finalize the report in order to meet the August "deadline." This, without their having had the time to review and consider reams of this very pertinent documentation, some of which Committee staff provided to NCHSR/HCTA on August 2 and August 10. Additional such materials were provided to NCHSR/HCTA by DHHS on August 11. It is my understanding that still more of this documentation has yet to be submitted by FDA to NCHSR/HCTA.
>
> Assuming that HCFA relied upon the seriously deficient NCHSR/HCTA assessment report to make a final decision on the reimbursement rate reductions, one can only conclude that HCFA's decision process was flawed.
>
> In light of these very distressing and shocking developments, I very strongly urge you again to take a personal interest in these matters which affect the safety and well-being of all dialysis patients. Specifically, I urge you to consider immediate withdrawal of the dialysis reimbursement reductions until NCHSR/HCTA has had sufficient time to evaluate the materials cited above for inclusion in its final assessment report and recommendation.
>
> Thank you for your cooperation and assistance in this important matter.

Signed "Sincerely, John Heinz, Chairman."

Mr. Michie. Mr. Erlichman, had you ever seen or read or been made aware of this August 15, 1986, letter to Secretary Bowen from Senator Heinz prior to your appearance here today?

Mr. Erlichman. That was a long question.

I don't believe I have seen this before. I don't believe I have read this before. It might have been as late as yesterday that I was made aware that such a memorandum existed.

Mr. Michie. Such a letter?

Mr. Erlichman. That the letter existed, but I believe I have seen it or read it prior to this.

Mr. Michie. Prior to your coming here?

Mr. Erlichman. That's correct.

Mr. Michie. Where you given any detail? did anyone share details of this letter with you prior to your appearance here today?

Mr. Erlichman. The only relationship—no, I was not. I was told that you had informed Dr. Carter, had made similar comments to him about the document, and I didn't know—I don't believe I knew that that was being put into a letter by the Senator to the Secretary.

Mr. Michie. The August 15, 1986, letter to Secretary Bowen from Senator Heinz will be identified as exhibit 2 in this deposition record. The subpoena served on Mr. Erlichman on August 15 of this year will be identified as exhibit 3 of this deposition record.

[Exhibits 2 and 3 were marked and included in the record.]

Mr. Michie. the notice of deposition submitted to Mr. Erlichman on that same date, August 15, 1986, will be identified as exhibit 4 of this deposition record.

[Exhibit 4 was marked and included in the record.]

Mr. Michie. Now, I believe we need to take up the matter of a statement that was delivered earlier on behalf of the deponent this morning, the statement by Mr. Riseberg, and so now I will defer to Mr. Morgan Frankel of the Senate Legal Counsel's Office.

Mr. Frankel. Could the court please administer the oath?

Mr. Riseberg. Before the oath is administered, I would like to ask the court reporter a couple of questions, please.

Are you the chairman of the Senate Special Committee on Aging.

The Reporter. No.

Mr. Riseberg. Are you a member of the Senate Special Committee on Aging?

The Reporter. No.

Mr. Frankel. The committee would be happy to stipulate that the court reporter is not a U.S. Senator.

Mr. Riseberg. Thank you.

Since Mr. Albert Sparks is neither chairman of the committee nor a member of the committee, his administation of the oath is of no legal significance.

Mr. Erlichman is, of course, prepared to answer truthfully to the best of his knowledge.

Mr. Frankel. Would the court reporter please administer the oath?

The Reporter. Would you raise your right hand, Mr. Erlichman?

Mr. **Erlichman**. For the record, I'm not really sure whether to take the oath or not.

We started the hearings and I answered the questions. I would like to continue to answer them in that manner. Based on how the Department feels in this matter, I feel it would be inappropriate to take the oath, although I am not exactly sure what to do.

I will not take it based on their feelings on this matter.

Mr. **Michie**. Mr. Erlichman, if I may just say something at this point, Senator Heinz as chairman of this committee did not subpoena the Department of Health and Human Services, nor did he subpoena the Public Health Service. He subpoenaed you as a individual who happens to work within those organizations.

Mr. **Riseberg**. Does the notice of deposition refer to Mr. Erlichman as a Health Science Analyst, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service, U.S. Department of Health and Human Services, Rockville, MD?

Mr. **Frankel**. The subpoena notice and the notice to the deposition are in the records and speak for themselves.

Mr. **Riseberg**. They were served upon Mr. Erlichman at his place of employment, I believe.

Mr. **Frankel**. Mr. Erlichman, did you receive a notice that your deposition would be taken, and a subpoena directing you to appear to testify at this deposition of the Special Committee on Aging?

Mr. **Erlichman**. I received a subpoena at work to appear.

Mr. **Frankel**. And notice of taking deposition with the subpoena?

Mr. **Erlichman**. I would have to check.

Mr. **Riseberg**. Here is a copy of it.

Mr. **Erlichman**. I believe so. Yes.

Mr. **Frankel**. Did you receive with the subpoena a copy of the rules of the Special Committee on Aging?

Mr. **Erlichman**. Yes.

Mr. **Frankel**. Have you had an opportunity to examine those rules?

Mr. **Erlichman**. Briefly, and general counsel has also examined those rules.

Mr. **Frankel**. Would you like to examine them at greater length? They are available.

Mr. **Erlichman**. I rely on general counsel.

Mr. **Frankel**. I refer your attention to committee rule 6.3, which provides "Witnesses shall be examined upon oath administered by an individual authorized by local law to administer oaths."

Do you understand that obligation?

Mr. **Riseberg**. Well, you are the witness.

Mr. **Erlichman**. If you want to elaborate on that, you might.

Mr. **Frankel**. I just want to know if you understand what that obligation means.

Mr. **Erlichman**. A local D.C.——

Mr. **Riseberg**. Do you understand the words, I take it, the sentence?

Mr. **Erlichman**. I understand the words.

Mr. **Frankel**. That there is an obligation to take an oath, and your have refused on advice of counsel to take an oath?

Mr. ERLICHMAN. On the advice of counsel who finds that the legality of this proceeding is doubtful, and that my participation should not be compelled by subpoena or governed by its terms, I have decided not to take the oath, yes.

Mr. FRANKEL. I'm sorry. Excuse me.

I refer you to section C-1 of the Committee System Reorganization Amendments of 1977, subparagraph (f) of which authorizes the Special Committee on Aging to require by subpoena the attendance of witnesses, and subparagraph (g), which authorizes the committee to take depositions.

Mr. RISEBERG. Do you have a copy of that?

Mr. ERLICHMAN. May I see that, please?

Mr. FRANKEL. It is a matter of public record. I am showing a copy of the witness.

Mr. ERLICHMAN. This is dated——

Mr. FRANKEL. It was enacted in 1977.

Mr. ERLICHMAN. And it is still——

Mr. FRANKEL. It is the resolution authorizing and charging the Special Committee on Aging.

Mr. ERLICHMAN. OK. Thank you.

Mr. RISEBERG. For the record, I notice that C-2 says that chairman of the select committee or any member thereof may administer oaths to witnesses. We have already established, have we not, that Mr. Sparks is neither.

Mr. FRANKEL. That's true. He does have that power.

I further refer you to the appendix to section 1192——

Mr. RISEBERG. I want to clarify what I said. He is neither a Senator——

Mr. MICHIE. Are you asking the question?

Mr. RISEBERG. I am just trying to make it clear that he is not one of the people listed in the rules as authorized to administer oaths.

Mr. ERLICHMAN. Can I have an answer to that?

I would like a response. Is that correct?

Mr. FRANKEL. I am not going to debate here the committee's authority. I believe the committee's authority is firmly established in law. Your counsel has advised you differently. If you choose to rely on his counsel, that is your option. I am not going to attempt to persuade you otherwise, or to get into a debate here. That will have to be resolved in another way.

Mr. ERLICHMAN. I would like that to be resolved in another way.

Mr. FRANKEL. I refer your attention to section 192 of title II of the United States Code which provides criminal penalties for contempt for a witness' refusal to testify before a congressional committee.

Are you aware of the existence of criminal penalties for refusal to testify under oath before a congressional committee?

Mr. ERLICHMAN. That has been discussed with me by counsel, and I am not refusing to testify. We have cooperated in the past, and I have come here this morning to provide responses to your questions.

Mr. FRANKEL. That obligation includes the obligation to testify under oath.

Mr. ERLICHMAN. The previous discussion has shown here some controversy regarding that that has to be resolved.

Mr. **Frankel**. That's correct. I simply want to establish your understanding.

Mr. **Erlichman**. I have been made aware of it.

Mr. **Frankel**. That if the committee's understanding of its authority is correct, your refusal of the obligation to testify under oath could be punished by criminal contempt.

Mr. **Riseberg**. Of course, that is a legal conclusion that is simply a matter of speculation.

Mr. **Michie**. That is also a matter of record.

Mr. **Frankel**. My question included the parenthetical, if the committee's view of its authority is correct. I simply want to establish not that the witness agrees with the committee, but that the witness understands that if the committee's view of its authority is correct, the witness, by refusing to take the oath, is putting himself in possible criminal jeopardy, and I would simply like an answer as to whether the witness has had that obligation explained to him.

Mr. **Riseberg**. The witness has been counseled. I think the witness' reaching any legal conclusions is really beyond anything that he needs to respond to. If he wishes to, he may do so.

Mr. **Erlichman**. That's sufficient.

Mr. **Frankel**. Will the court reporter please administer the oath, having had the obligation and the possible criminal penalties explained to the witness.

The **Reporter**. Would you raise your right hand?

Mr. **Erlichman**. Nothing has changed since the earlier response.

Mr. **Frankel**. You are refusing to take the oath?

Mr. **Erlichman**. I am refusing to take the oath on advice of counsel and the questioning of the legality of these proceedings.

Mr. **Frankel**. Would counsel please state the basis for his advice to the witness instructing the witness not to take the oath?

Mr. **Riseberg**. I don't think I need explain beyond the fact that the person administering the oath is neither the chairman of the committee nor a member of the committee.

The Senate rules establishing the committee make it quite clear that those are the people who are authorized to administer the oath.

Even the Senate rules which are not—would, of course, be of no legal significance insofar as they were not authorized by the appropriate resolutions of the Senate, the full Senate, require that the person administering the oath be authorized by local law to administer the oath, since clearly insofar as the resolution that you cited refers to oaths being administered solely by members of the committee.

Therefore, one must conclude that Mr. Sparks is not an individual authorized by local law to administer oaths. This is not a full and complete legal analysis, but I think it will suffice for purposes of indicating at least the solid basis for Mr. Erlichman's decision.

Mr. **Michie**. For the record, Mr. Erlichman, are you at this time declining, on the advice of Mr. Riseberg, to honor the subpoena served on you by me and signed by Senator John Heinz, chairman of this committee, on August 15, 1986?

Mr. **Riseberg**. I think we ought to clarify the question.

Mr. **Michie**. Please, counsel, just a moment.

Mr. ERLICHMAN. Could you please clarify the question? I am here.

Mr. MICHIE. I am asking you. That is why I asked the question. What I am asking you is, are you declining to honor the subpoena signed by Senator John Heinz and served on you on August 15, 1986, to appear here on this 26th day of August in order to give sworn testimony in this deposition? Are you declining to honor that subpoena under those circumstances?

Mr. ERLICHMAN. I am declining to take the oath. If that——

Mr. RISEBERG. There is no one here authorized to swear him in.

Mr. ERLICHMAN. Based on counsel's advice.

Mr. MICHIE. This deposition will be recessed at this point, noting that this matter will be referred to the chairman of the committee for disposition, and this deposition will be recessed until further notice.

[Time noted, 9:43 a.m.]

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
CHARLES E. GRASSLEY, IOWA
PETE WILSON, CALIFORNIA
JOHN W. WARNER, VIRGINIA
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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

July 23, 1986

Honorable Otis R. Bowen, M.D.
Secretary,
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

As Chairman of the Special Committee on Aging, I am writing to share with you my deep concern and dismay over learning that department officials presented inaccurate and misleading testimony before the Committee at the March 6, 1986 hearing on the reuse of dialysis devices.

I recently learned of a memorandum prepared by John Marshall, Ph.D., Director, National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA), for Robert E. Windom, M.D., Assistant Secretary for Health. The memorandum, a copy of which I have enclosed, is based upon the NCHSR/HCTA's "Assessment of Medical Technology: Reuse of Hemodialysis Devices Labeled for Single Use Only" initiated in April 1986, following the Committee's March 6 hearing.

This alarming and shocking memorandum reveals all too clearly a severe breakdown in communications and coordination among the agencies responsible for the safety and well-being of dialysis patients: the National Institutes of Health (NIH); the Food and Drug Administration (FDA); the Health Care Financing Administration (HCFA); and the Centers for Disease Control (CDC). Indeed, as Dr. Marshall observed in his memorandum, these agencies "have had a long but non-productive involvement with [reuse] issues." Moreover, it confirms many of the serious concerns regarding the safety of reuse that were raised in the Committee's staff report as well as in testimony, but denied or dismissed by witnesses representing the Department of Health and Human Services (DHHS). The Marshall memorandum states, however, that the NCHSR/HCTA assessment "uncovered serious omissions and inaccuracies in the testimony."

The memorandum indicates that Dr. Marshall, the Department's principal witness at the March 6 hearing, was himself the victim of misinformation and lack of information regarding the safety and efficacy of dialysis device reprocessing and reuse. Further, the findings of the NCHSR/HCTA assessment serve as a strong indictment of failure on the part of those who were responsible for providing Dr. Marshall with accurate and complete information in preparation for his testimony.

The Marshall memorandum establishes that much of the information and data previously used to support the "safety" of reuse, such as the NIH report "Multiple Use of Hemodialyzers" (e.g., the Dean report), is unreliable.

I trust now that you can understand and appreciate why I continue to be deeply concerned for the health and safety of this nation's 80,000 dialysis patients, many of whom have falsely and wrongly been misled into believing that there are no risks associated with the reuse of their dialysis devices.

In light of the NCHSR/HCTA assessment findings and the most recent outbreaks of life-threatening bacterial infections in dialysis patients subjected to reuse, I strongly urge you to take immediate action on Dr. Marshall's recommendation:

> "The Public Health Service needs to take a clinically and scientifically based stand with respect to this issue. We need to communicate that directly and emphatically to the Health Care Financing Administration, even if that means recognizing that our earlier testimony was flawed."

In addition, and in the interest of adequately protecting dialysis patients from any further threat of harm and injury, I am requesting that you take immediate action on my earlier recommendations: (1) require dialysis clinics to adequately inform their patients of the risks of reuse and prohibit the clinics from coercing and forcing patients to reuse their dialysis devices; (2) withdraw HCFA's proposed regulations that would lower the dialysis reimbursement rate and, consequently, force still more clinics to reprocess and reuse dialysis devices; (3) conduct appropriate and controlled preclinical and clinical testing to determine the safety and efficacy of the reprocessing and reuse of dialysis devices; and (4) direct the FDA to impose its good manufacturing practice regulations on reprocessors of dialysis devices, and to develop uniform safety standards for the reprocessing and reuse of dialysis devices and supplies.

Should you or your staff have any questions regarding this request, please have your staff contact Jim Michie or David Schulke at 224-5364.

Thank you for your cooperation and assistance in this important matter.

Sincerely,

John Heinz
John Heinz,
Chairman

Enclosure

JH:jfm

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date JUL 8 1986

From Director, National Center for Health Services Research
and Health Care Technology Assessment

Subject Hemodialyzer Reuse

To Assistant Secretary for Health

ISSUE

As HCFA continues to ratchet down the reimbursement rate for hemodialysis, concern has grown on the part of hemodialysis patients and the Congress, with respect to the safety and efficacy of the reuse of dialysis equipment, including bloodlines, tubing, transducer caps, and filters. Senator Heinz was sharply critical of the Public Health Service's role in this process during hearings which he conducted on March 6 of this year. The involvement of NCHSR is only recent, but NIH, FDA and CDC have had a long but non-productive involvement with these issues. During the March 6 hearing, at which I was the witness for the PHS, accompanied by John Villforth of FDA, we agreed to do an assessment of the state-of-the-art. As events have unfolded, it is clear that the March 6 testimony was not based on all of the germane facts and that we may need to take a position counter to that which we argued on March 6. We need to ascertain a PHS position and inform HCFA of that position so as to minimize embarrassment for the Department.

BACKGROUND

The March 6 hearing focused on the following issues:

1. Does adequate information exist to determine what standards are necessary for adequate disinfection of dialysis equipment?
2. How many uses of a given unit should be permitted before its integrity is compromised?
3. What is the Department doing to monitor adverse effects?
4. Are patients being fully informed of the risks attendant to dialyzer reuse and is their freedom of choice being compromised?

In 1978, the Congress directed NIH to carry out a study of hemodialysis. A contract was let which led to release of the Dean Report in 1981. The Dean Report was subsequently revised in 1982. The essential conclusion of the Dean Report was that processing, when properly effected, could yield a hollow tube filter equivalent to a new filter. Arthur D. Little, Inc. was a subcontractor to this effort and it released a criticism of the Dean report arguing that its efforts had been improperly represented and that the report was limited to an in vitro assessment which ignored clinical data.

In 1982, a departmental Interagency Task Force recommended clinical trials to address the questions identified above. That report was not sent forward from the Public Health Service to the Secretary's office. Instead, in 1983 an ESRD Coordinating Committee was established. The ESRD Coordinating Committee recommended against clinical trials on the grounds that they were not necessary and would be too expensive. They did recommend that FDA establish a registry to track events.

One of the major pursuits of Senator Heinz at the hearing was a demand that the Department undertake rigorous clinical trials. As the witness, I argued that even though there had been an increase from 15 to 65 percent of the Centers which were reusing the dialysis equipment, it was found that there had been no increase in reports of mortality or morbidity. In fact, some literature suggests that there are more untoward events with first use filters than with subsequent use filters. The apparent increase in reuse was probably stimulated by the reimbursement caps effected by HCFA. Interestingly, the price of a dialyzer unit has dropped from the $28 to $30 range to a $10 to $12 range. Reprocessing costs between $7 and $9, so at the present, the cost differential is not great.

FDA labels these devices for single use. But, it has approved reprocessing equipment. There are, however, no guidelines for the use of approved reprocessing equipment. Voluntary standards have been under development by the Association for the Advancement of Medical Instrumentation for several years, but their release continues to be delayed. In any case, they do not address the question of reuse for bloodlines, tubing, the transducer caps, or the transducer filters. Senator Heinz has argued that there should be rigorous standards which are enforced by HCFA. He faults the Public Health Service for not developing such standards. He is well aware that the buck passes from one agency to another with no one accepting responsibility for action. In part, that reflects HCFA's lack of interest in standards because it doesn't have resources for compliance monitoring and enforcement.

Senator Heinz also argues that the reprocessing of filters should be subject to the Good Manufacturing Practices Act. FDA has maintained that the reuse of the filter is a clinical matter and FDA does not regulate or monitor the practice of medicine.

FDA has approved the marketing of two disinfectants which are advertised as being less toxic than formaldehyde. One of these ReNew-D has been implicated in recent outbreaks of bacteremia in which at least one person has died. Two of these outbreaks have been in Florida. One each have occurred in Texas and California. The distributer of ReNew-D, Alcide has withdrawn it from the market.

CDC has investigated a 1983 outbreak in Louisiana in which 27 individuals were affected, 14 of whom died. CDC is investigating the current outbreaks. The question remains unanswered whether this was because of a failure of the disinfectant, or whether it was a matter of improper processing. Although I testified, based on information received from CDC, that they have a standard expressing the adequacy of the use of 4% formaldehyde solution, this is apparently not a formal standard and indeed there are no CDC guidelines for disinfection. We need to have a formal position with respect to which disinfectants are effective, at what strength can they be used, and what are the absolutely essential standards for processing.

In each of the last two issues of the MMWR, CDC has carried articles with respect to dialysis issues. In neither case was the reference to the fact that the Public Health Service was undertaking an assessment. In the first of these, MMWR addressed the issue of exposure to formaldehyde by individuals engaged in reprocessing. Concern among employees of dialysis centers over exposure to formaldehyde is thought to be one of the issues stimulating the use of alternative disinfectants. In last Friday's MMWR, CDC reported on the current outbreaks, with an editorial note calling for more clinical studies. Again, there was no reference to other PHS efforts. Both of these publications will be seized upon by Senator Heinz's staff and used to criticize us.

During my testimony, we reported that HCFA and NIH has established a registry which would make it possible to look at issues affecting reuse. Apparently that information was not correct. There has not yet been a decision as to whether or not the registry will collect information on this issue, or whether it will be analyzed for this purpose.

On June 12 of this year, HCFA participated in a briefing of the Under Secretary prior to a meeting between the Under Secretary and representatives of the dialysis patients organization. A briefing memo from HCFA to the Under Secretary is presently in clearance within the Department.

After the hearing, Dr. Macdonald directed me to carry out an assessment of dialyzer reuse. In the course of carrying out that assessment, it has become evident that communication within the Public Health Service is less than adequate. We uncovered serious omissions and inaccuracies in the testimony which had been prepared based on facts made available last March. Some of these only came to light the day before the comment period for the assessment expired, when we received several hundred pages of information from Senator Heinz. Included in that were internal PHS documents that had not previously been shared with us. On the strength of that, I requested an extension to July 10 for completing our report. However, the recent outbreaks of bacteremia, and additional information that has unfolded from that process, suggest that a report at this time might not be appropriate.

ACTION

The PHS needs to take a clinically and scientifically based stand with respect to this issue. We need to communicate that directly and emphatically to the Health Care Financing Administration, even if that means recognizing that our earlier testimony was flawed.

John E. Marshall, Ph.D.

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

WILLIAM S. COHEN, MAINE
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DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

August 15, 1986

The Honorable Robert E. Windom, M.D.
Assistant Secretary for Health
U.S. Public Health Service
U.S. Department of Health and
Human Services
Room 716G, Hubert H. Humphrey Bldg.
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Windom:

I am writing to share with you very distressing developments regarding the recently completed assessment of reuse of disposable dialysis devices by the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA).

The Aging Committee's ongoing investigation into reprocessing and reuse of dialysis devices has revealed inexplicable activities within the Public Health Service (PHS) and the Health Care Financing Administration (HCFA). Specifically, I am referring to the abrupt termination on August 6, 1986 of the NCHSR/HCTA assessment, and HCFA's premature publication on August 15, 1986 of reductions in Medicare's dialysis reimbursement rates which will become effective on October 1, 1986.

As you know, HCFA relies very heavily upon NCHSR/HCTA's scientific and technological expertise in developing and finalizing its actions regarding administration of health care financing. I must assume that such was the case in HCFA's decision this week to proceed with the dialysis reimbursement reductions. Further, I must assume that HCFA relied upon the NCHSR/HCTA's draft assessment report submitted to you on August 6, 1986.

I deeply regret to inform you that the NCHSR/HCTA report is seriously flawed. The report lacks critically pertinent information concerning deaths, serious injuries, extremely poor reprocessing procedures in dialysis clinics, and numerous deficiencies in manufacturing practices of firms that market dialysis and reprocessing devices.

I was interested in your comment to me last Wednesday evening indicating that the information forwarded to NCHSR/HCTA by Committee staff had already been in their possession and had been fully considered. I am not sure how to reconcile this with reports from NCHSR/HCTA that the assessment report was hastily finalized to meet the August 6 "deadline," without time to review and consider reams of very pertinent documentation, some of which Committee staff provided to NCHSR/HCTA on August 2 and August 10 and other materials that were provided to NCHSR/HCTA by the Department on August 11. It is my understanding that still more of this documentation has yet to be submitted by FDA to NCHSR/HCTA.

I plan to share this information with Secretary Bowen in the hope that he would consider immediate withdrawal of HCFA's dialysis reimbursement reductions, until NCHSR/HCTA has had sufficient time to complete its assessment so that HCFA can make an informed decision on the reimbursement issue.

In light of these findings, I very strongly urge you to permit NCHSR/HCTA time enough to perform a thorough and complete assessment drawing upon all available documentation on this vital subject.

Thank you for your cooperation and assistance in this important matter.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

JH:jfm

UNITED STATES OF AMERICA

Congress of the United States

To Martin N. Erlichman, Health Sciences Analyst, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service, U.S. Department of Health and Human Services, Rockville, Maryland, *Greeting:*

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* August 26, *19*86, *at* nine *o'clock* a.m., *at their committee room* SD-G33 in the Dirksen Senate Office Building, *then and there to testify what you may know relative to the subject matters under consideration by said committee,* in sworn deposition to be conducted by committee staff.

Hereof fail not, *as you will answer your default under the pains and penalties in such cases made and provided.*

To James F. Michie, Chief Investigator *to serve and return.*

Given under my hand, by order of the committee, this 14th *day of* August, *in the year of our Lord one thousand nine hundred and* eighty-six.

John Heinz

Chairman, Committee on Aging

UNITED STATES OF AMERICA

Congress of the United States

Notice of
Senate Deposition

To Martin N. Erlichman, Health Sciences Analyst, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service, U.S. Department of Health and Human Services, Rockville, Maryland.

, **Greeting:**

Please *take notice that at* nine *o'clock* a.m., *on* August 26 *19*86 at Rm. SD-G33, Dirksen Senate Office Bldg., Washington, D.C., J.F. Michie, D.G. Schulke & C.C. Jennings *, of the staff of the* Special *committee on* Aging *of the Senate of the United States, will take your deposition on oral examination concerning what you may know relative to the subject matters under consideration by said* Special *committee. The deposition will be taken before a notary public, or before some other officer authorized by local law to administer oaths; it will be taken pursuant to the* Special *committee's rules, a copy of which are attached.*

Given *under my hand, by authority vested in me by the* Special *committee, on* August 14, *19*86.

John Heinz
JOHN HEINZ
Chairman

GPO [illegible]

TUESDAY, AUGUST 26, 1986

Washington, DC.

Deposition of Dr. Enrique D. Carter, called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 10:10 a.m., before Albert R. Sparks, a notary public in and for the District of Columbia.

Present:

For the Special Committee on Aging:

James F. Michie, chief investigator, U.S. Senate, Special Committee on Aging, room SDG-33, Dirksen Senate Office Building, Washington, DC 20510 (202) 224-5364.

David Schulke, committee investigator.

Christopher Jennings, committee staff member.

Morgan Frankel, Esq., Office of the Senate Legal Counsel.

For the U.S. Public Health Service:

Richard J. Riseberg, Esq., chief counsel, Public Health Service, room 4-A-53, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 (301) 443-2644.

Mr. MICHIE. We are on the record.

My name is James F. Michie. I am chief investigator for the Special Committee on Aging of the U.S. Senate.

Present with me today in room SDG-31 of the Dirksen Senate Office Building are Committee Investigator David Schulke, Committee Staff Member Christopher Jennings, Morgan Frankel of the Senate legal counsel's office, the notary public and stenographer, Albert Sparks, and Enrique D. Carter, M.D., Director of the Office of Health Technology Assessment in the National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service.

Dr. Carter is accompanied by Richard Riseberg, of the Office of General Counsel, U.S. Public Health Service.

On August 15 of this year, Dr. Carter was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging, for the purpose of being deposed by the committee staff on this 26th day of August, 1986.

A copy of the subpoena and notice of deposition will be made a part of this deposition record.

The subpoena is identified as exhibit 1, the notice of deposition is identified as exhibit 2.

[Exhibits 1 and 2 were marked and included in the record.]

Mr. MICHIE. Prior to being sworn in, Dr. Carter, I want to remind you that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury.

Are you ready to proceed?

Mr. RISEBERG. I have a statement for the record.

Mr. MICHIE. We recognize Mr. Riseberg, of the Office of General Counsel, U.S. Public Health Service.

Mr. Riseberg?

Mr. RISEBERG. For the record, I am Richard J. Riseberg, chief counsel for the Public Health Service. I have been designated by the Department to accompany Dr. Carter to this interview.

The Department has asked me to indicate that it is volunteering to make Dr. Carter available in order to cooperate with the Senate Special Committee on Aging in connection with its study of issues related to dialyzer reuse, and he is participating in today's interview solely on that basis.

He has been advised by attorneys for the Department that the subpoena recently served upon him is of doubtful legality and that the Department does not regard his participation to be compelled by the subpoena or governed by its terms.

Nevertheless, subject to this understanding, Dr. Carter looks forward to answering any questions you may have.

Mr. MICHIE. Dr. Carter, do you accept the statement by Mr. Riseberg in your behalf?

Dr. CARTER. I do.

Mr. MICHIE. I think it is essential for this record, Dr. Carter, that we obtain from you your understanding of this proceeding and the reasons for your appearance here today.

Are you aware of Senator Heinz' letters of July 23 and August 15, 1986, to Dr. Otis Bowen, Secretary of the Department of Health and Human Services? Are you aware of those letters, and have you seen them? We would now like to provide you copies of those letters.

Dr. CARTER. Yes, I would——

Mr. MICHIE. We would like you to take your time and read both those letters and, as you do so, Mr. Schulke will read into the record the first of those letters, the July 23, 1986, letter from Senator Heinz to Secretary Bowen. This shall be indentified as exhibit 3 of this deposition record.

[Exhibit 3 was marked and included in the record.]

Mr. MICHIE. Mr. Schulke?

Mr. SHULKE. On the letterhead of the U.S. Senate, Special Committee on Aging, letter dated July 23, 1986, addressed to Hon. Otis R. Bowen, M.D., Secretary, Department of Health and Human Services.

Dear Mr. SECRETARY: As Chairman of the Special Committee on Aging, I am writing to share with you my deep concern and dismay over learning that department officials presented inaccurate and misleading testimony before the Committee at the March 6, 1986 hearing on the reuse of dialysis devices.

I recently learned of a memorandum prepared by John Marshall, Ph.D., Director, National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) for Robert E. Windom, M.D., Assistant Secretary for Health. The memorandum, a copy of which I have enclosed, is based upon the NCHSR/HCTA's "Assessment of Medical Technology: Resuse of Hemodialysis Devices Labeled for Single Use Only" initiated in April 1986, following the Committee's March 6 hearing.

This alarming and shocking memorandum reveals all too clearly a severe breakdown in communications and coordination among the agencies responsible for the safety and well-being of dialysis patients: the National Institutes of Health (NIH); the Food and Drug Administration (FDA); the Health Care Financing Administration (HCFA); and the Centers for Disease Control (CDC). Indeed, as Dr. Marshall observed in his memorandum, these agencies "have had a long but non-productive involvent with [reuse] issues." Moreover, it confirms many of the serious concerns regarding the safety of reuse that were raised in the Committee's staff report as well as in testimony, but denied or dismissed by witnesses representing the Department of Health and Human Services (DHHS). The Marshall memorandum states, however, that the NCHSR/HCTA assessment "uncovered serious omissions and inaccuracies in the testimony."

The memorandum indicates that Dr. Marshall, the Department's principal witness at the March 6 hearing, was himself the victim of misinformation and lack of information regarding the safety and efficacy of dialysis device reprocessing and reuse. Further, the findings of the NCHSR/HCTA assessment serve as a strong indictment of failure on the part of those who were responsible for providing Dr. Marshall with accurate and complete information in preparation for his testimony.

The Marshall memorandum establishes that much of the information and data previously used to support the "safety" of reuse, such as the NIH report "Multiple Use of Hemodialyzers" (e.g., the Deane report), is unreliable.

I trust now that you can understand and appreciate why I continue to be deeply concerned for the health and safety of this nation's 80,000 dialysis patients' many of whom have falsely and wrongly been misled into believing that there are no risks associated with the reuse of their dialysis devices.

In light of the NCHSR/HCTA assessment findings and the most recent outbreaks of life-threatening bacterial infections in dialysis patients subjected to reuse, I strongly urge you to take immediate action on Dr. Marshall's recommendation:

"The Public Health Service needs to take a clinically and scientifically based stand with respect to this issue. We need to communicate that directly and emphatically to the Health Care Financing Administration, even it that means recognizing that our earlier testimony was flawed."

In addition, and in the interest of adequately protecting dialysis patients from any further threat of harm and injury, I am requesting that you take immediate action on my earlier recommendations: (1) require dialysis clinics to adequately inform their patients of the risks of reuse and prohibit the clinics from coercing and forcing patients to reuse their dialysis devices; (2) withdraw HCFA's proposed regulations that would lower the dialysis reimbursement rate and, consequently, force still more clinics to reprocess and reuse dialysis devices; (3) conduct appropriate and controlled preclinical and clinical testing to determine the safety and efficacy of the reprocessing and reuse of dialysis devices, and (4) direct the FDA to impose its good manufacturing practice regulations on reprocessors of dialysis devices, and to develop uniform safety standards for the reprocessing and reuse of dialysis devices and supplies.

Should you or your staff have any questions regarding this request, please have your staff contact Jim Michie or David Schulke at 224-5364.

Thank you for your cooperation and assistance in this important matter.

Sincerely, signed "John Heinz, Chairman," with an enclosure which is the July 8, 1986, memo.

Mr. Michie. At this point, Dr. Carter, I would like to ask you, have you prior to your appearance here today seen this letter and read it?

Dr. Carter. I don't believe I have seen this letter in total. I believe portions of it were read to me. I'm trying to remember. I don't think—I know I was not forwarded a copy of this letter.

Mr. Michie. At this time, I would now ask Mr. Schulke to read into the record the attachment to that letter, which is the July 8, 1986, memo to Dr. Robert Windom, Assistant Secretary for Health, from Dr. John Marshall, who is Director of the National Center for Health Services Research and Health Care Technology Assessment, and also the superior, the immediate supervisor, of Dr. Enrique Carter, the deponent here today.

Mr. Schulke?

Mr. Schulke. On the letterhead of the Department of Human Services, Public Health Service.

ISSUE

As HCFA continues to ratchet down the reimbursement rate for hemodialysis, concern has grown on the part of hemodialysis patients and the Congres, with respect to the safety and efficacy of the reuse of dialysis equipment, including bloodlines, tubing, transducer caps, and filters. Senator Heinz was sharply critical of the Public Health Service's role in this process during hearings which he conducted on March 6 of this year. The involvement of NCHSR is only recent, but NIH, FDA and CDC have had a long but non-productive involvement with these issues. During the March 6 hearing, at which I was the witness for the PHS, accompanied by John Villforth of FDA, we agreed to do an assessment of the state-of-the-art. As events have unfolded, it is clear that the March 6 testimony was not based on all of the germane facts and that we may need to take a position counter to that which we argued on March 6. We need to ascertain a PHS position and inform HCFA of that position so as to minimize embarrassment for the Department.

BACKGROUND

The March 6 hearing focused on the following issues:

1. Does adequate information exist to determine what standards are necessary for adequate disinfection of dialysis equipment?
2. How many uses of a given unit should be permitted before its integrity is compromised?
3. What is the Department doing to monitor adverse effects?
4. Are patients being fully informed of the risks attendant to dialyzer reuse and is their freedom of choice being compromised?

In 1978, the Congress directed NIH to carry out a study of hemodialysis. A contract was let which led to release of the Deane Report in 1981. The Deane Report was subsequently revised in 1982. The essential conclusion of the Deane Report was that processing, when properly effected, could yield a hollow tube filter equivalent to a new filter. Arthur D. Little, Inc. was a subcontractor to this effort and it released a criticism of the Deane report arguing that its efforts had been improperly represented and that the report was limited to an in vitro assessment which ignored clinical data.

In 1982, a departmental Interagency Task Force recommended clinical trials to address the questions identified above. That report was not sent forward from the Public Health Service to the Secretary's office. Instead, in 1983 an ESRD Coordinating Committee was established. The ESRD Coordinating Committee recommended against clinical trials on the grounds that they were not necessary and would be too expensive. They did recommend that FDA establish a registry to track events.

One of the major pursuits of Senator Heinz at the hearing was a demand that the Department undertake rigorous clinical trials. As the witness, I argued that even though there had been an increase from 15 to 65 percent of the Centers which were reusing the dialysis equipment, it was found that there had been no increase in reports of mortality or morbidity. In fact, some literature suggests that there are more untoward events with first use filters than with subsequent use filters. The apparent increase in reuse was probably stimulated by the reimbursement caps effected by HCFA. Interestingly, the price of a dialyzer unit has dropped from the $28 to $30 range to a $10 to $12 range. Reprocessing costs between $7 and $9, so at the present, the cost differential is not great.

FDA labels these devices for single use. But, it has approved reprocessing equipment. There are, however, no guidelines for the use of approved reprocessing equipment. Voluntary standards have been under development by the Association for the Advancement of Medical Instrumentation for several years, but their release continues to be delayed. In any case, they do not address the question of reuse for bloodlines, tubing, the transducer caps, or the transducer filters. Senator Heinz has argued that there should be rigorous standards which are enforced by HCFA. He faults the Public Health Service for not developing such standards. He is well aware that the buck passes from one agency to another with no one accepting responsibility for action. In part, that reflects HCFA's lack of interest in standards because it doesn't have resources for compliance monitoring and enforcement.

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ACTION

The PHS needs to take a clinically and scientifically based stand with respect to this issue. We need to communicate that directly and emphatically to the Health Care Financing Administration, even if that means recognizing that our earlier testimony was flawed.

It is signed "John."

Mr. **MICHIE**. Dr. Carter, do you recall ever having seen and read this particular memo prior to your appearance here today?

Dr. **CARTER**. Yes, sir.

Mr. **MICHIE**. I would now ask Mr. Schulke to read into the record exhibit No. 4 for this deposition record, a letter dated August 15, 1986, to Secretary Otis Bowen, from Senator John Heinz.

Mr. Schulke?

Mr. **RISEBERG**. Could I ask a technical question? That was exhibit 2 in the Erlichman deposition. Is the numbering changed?

Mr. **MICHIE**. This is a separate deposition.

Mr. **RISEBERG**. I just wanted to be sure.

Mr. **MICHIE**. It will be a matter of record in both depositions. Please read.

Mr. **Schulke**. A letter on the letterhead of the U.S. Senate, Special Committee on Aging, August 15, 1986, addressed to Hon. Otis R. Bowen, M.D., Secretary of Health and Human Services.

Dear Mr. Secretary: I am writing to share with you my recent findings concerning a grave injustice that is being done to Medicare's 80,000 dialysis patients who are threatened by recent actions, within the Department of Health and Human Services.

The Aging Committee's ongoing investigation into reuse of disposable dialysis devices has revealed inexplicable and ill-conceived activities within the Public Health Service (PHS) and the Health Care Financing Administration (HCFA). Specifically, I am referring to the abrupt termination on August 6, 1986 of the assessment of reuse procedures by the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA), and HCFA's premature publication on August 15, 1986 of reductions in Medicare's dialysis reimbursement rates, which will become effective on October 1, 1986.

As you know, HCFA relies very heavily upon NCHSR/HCTA's scientific and technological expertise in developing and finalizing its actions regarding administration of health care financing. I must assume that such was the case in HCFA's decision this week to proceed with the dialysis reimbursement rate reductions. Further, I must assume that HCFA relied upon the NCHSR/HCTA's draft assessment report that was submitted to the Assistant Secretary for Health, Robert E. Windom, M.D., on August 6, 1986.

I deeply regret to inform you that the NCHSR/HCTA report is seriously flawed. The report lack critically pertinent information concerning deaths, serious injuries, extremely poor reprocessing procedures in dialysis clinics, and numerous deficiencies in manufacturing practices of firms that market dialysis and reproceesing devices.

The Committee's investigation has determined that the NCHSR/HCTA staff was forced to hastily finalize the report in order to meet the August "deadline." This, without their having had the time to review and consider reams of this very pertinent documentation, some of which Committee staff provided to NCHSR/HCTA on August 2 and August 10. Additional such materials wer provided to NCHSR/HCTA by DHHS on August 11. It is my understanding that still more of this documentation has yet to be submitted by FDA to NCHSR/HCTA.

Assuming that HCFA relied upon the seriously deficient NCHSR/HCTA assessment report to make a final decision on the reimbursement rate reductions, one can only conclude that HCFA's decision process was flawed.

In light of these very distressing and shocking developments, I very strongly urge you again to take a personal interest in these matters which affect the safety and well-being of all dialysis patients. Specifically, I urge you to consider immediate withdrawal of the dialysis reimbursement reductions until NCHSR/HCTA has had sufficient time to evaluate the materials cited above for inclusion in its final assessment report and recommendation.

Thank you for your cooperation and assistance in this important matter.

Signed "Sincerely, John Heinz, Chairman."

Mr. **Michie**. Dr. Carter, prior to your appearance here today, did anyone within the Department of Health and Human Services, or within the Public Health Service, ever share a copy of this letter with you?

Dr. **Carter**. No, sir.

Mr. **Michie**. I believe we have a matter concerning the statement read earlier into this record by Mr. Riseberg in behalf of the deponent, Dr. Carter. At this time, I would ask Mr. Frankel of the Senate Legal Counsel's Office to proceed.

Mr. **Frankel**. Will the court reporter please administer the oath to the witness.

Mr. **Riseberg**. Before that happens, do you stipulate that he is not a Member of the Senate?

Mr. **Frankel**. The court reporter is not a member of the U.S. Senate. He is a notary public authorized to administer oaths by local law.

Mr. **Riseberg**. Since Albert Sparks is not chairman of the committee, his administration of the oath is not of legal significance. Dr. Carter is prepared to answer truthfully to the best of his knowledge.

Mr. **Frankel**. Would the reporter please administer the oath to the witness.

The **Reporter**. Would you raise your right hand, Dr. Carter?

Dr. **Carter**. I would like to say that I am willing to appear voluntarily before this committee to answer any questions the committee may have. Given the advice of counsel and the statement that was read into the record at the opening of these proceedings, I am unclear as to what my role is here and in what capacity I am here, and would like to clarify that before receiving, or having an oath administered.

Mr. **Michie**. With whom would you like to consult for clarification, Dr. Carter?

Dr. **Carter**. Could I take a minute to consult with counsel?

Mr. **Michie**. Yes. Would you wish to do so in private?

Dr. **Carter**. Yes, sir.

Mr. **Michie**. All right, if you will come this way.

This deposition is recessed for purposes of the deponent to consult with counsel.

[Dr. Carter and his counsel leave the room.]

[Recess taken from 10:35 a.m. until 10:45 a.m.]

Mr. **Michie**. We are now back on the record after the deponent, Dr. Carter, has taken a few minutes to consult with Mr. Riseberg, counsel for the Public Health Service.

Mr. Frankel?

Mr. **Frankel**. Is there any change in your position at this point?

Dr. **Carter**. I would just like to say that I am willing to provide voluntary answers to questions.

Mr. **Frankel**. Are you willing to take an oath administered by the court reporter?

Dr. **Carter**. I'm willing to take an oath administered by a Member of Congress or the chairman of the committee.

Mr. **Frankel**. So I understand you are unwilling to take an oath, therefore, administered by the court reporter?

Dr. **Carter**. I would just like to reiterate that I am here to cooperate with the committee, and I wish to answer questions administered—asked—if I am able to do so voluntarily, and I would receive the oath if administered by a member of the committee or a Member of Congress or the chairman of the committee.

Mr. **Frankel**. Dr. Carter, did you receive a notice that your deposition would be taken and a subpoena directing you to appear to testify at this deposition at the Special Committee on Aging?

Dr. **Carter**. Yes, sir.

Mr. **Frankel**. Did you receive with the subpoena a copy of the rules of the Special Committee on Aging?

Dr. **Carter**. Yes, sir.

Mr. **Frankel**. Have you had an opportunity to examine those rules? Would you like additional time now to do so?

Dr. **Carter**. I have examined them, but I would like additional time to examine them further.

Mr. **Frankel**. Fine. I might refer your attention specifically to committee rule 6.3, which provides, "Witnesses shall be examined upon oath administered by an individual authorized by local law to administer oaths."

Do you understand the obligation to be examined upon oath?

Dr. **Carter**. I am advised that the obligation exists when appearing before the committee.

Mr. **Frankel**. You understand the meaning of that obligation, of that requirement?

Dr. **Carter**. The requirement to appear before the committee and its members and be sworn?

Mr. **Frankel**. The requirement that testimony be sworn under oath?

Dr. **Carter**. I understand the requirement to be sworn before the committee and its members, the chairman and the members of the committee.

Mr. **Frankel**. I refer your attention to 104–C–1 of the Committee System Reorganization Amendments of 1977.

Mr. **Riseberg**. Do you have a copy of that?

Mr. **Frankel**. [Handing to Mr. Riseberg.]

Mr. **Riseberg**. Fine.

Mr. **Frankel**. Subparagraph (f)—subparagraph (f) of which authorizes the Special Committee on Aging to require by subpoena the attendance of witnesses. And subparagraph (g) of which authorizes the committee to take depositions.

Mr. **Riseberg**. For purposes of completeness of the record, I also want to introduce C–2 of the same—is this a resolution?

Mr. **Frankel**. Senate Resolution 4.

Mr. **Riseberg**. That says the chairman of the Special Committee or any member thereof may administer oaths to witnesses.

Mr. **Frankel**. Dr. Carter, I further refer your attention to section 192 of title II of the United States Code——

Mr. **Riseberg**. I think he—he wants a chance to deal with this one.

Dr. **Carter**. I didn't understand what counsel just read. Where was that?

Mr. **Riseberg**. What he read was here——

Mr. **Michie**. Would you please read that aloud for the record?

Mr. **Riseberg**. I am just reiterating what Mr. Frankel read in C–1 which is, for purposes of this section the subcommittee is authorized in its discretion to require by subpoena or otherwise attendance of witnesses, et cetera, and (g), to take deposition and other testimony, and what I read into the record is a further provision in that document that says that the chairman of the special committee or that any member thereof may administer oaths to witnesses.

Mr. **Frankel**. I further refer your attention to section 1192 of title II of the United States Code which provides criminal penalties for contempt, for a witness' refusal to testify before a congressional committee.

Are you aware of the existence of criminal penalties for refusal to testify under oath before a congressional committee?

Again, I am not asking for you to agree with the legal position that your counsel has instructed you to take, or disagree. I am simply ascertaining that you understand there are criminal penalties for refusal to testify and you run the risk of those criminal penalties if indeed your counsel's advice is incorrect.

Dr. CARTER. Yes.

Mr. FRANKEL. Will the court reporter please administer the oath to the witness.

The REPORTER. Would you raise your right hand, please, Dr. Carter?

Dr. CARTER. I believe I would prefer to answer any questions to the congressional staff voluntarily, not under oath, any and all questions, and under oath before the chairman or the members of the committee.

Mr. FRANKEL. So you are declining to take an oath here today under the present circumstances?

Dr. CARTER. Yes.

Mr. FRANKEL. Will counsel for the witness please state the basis for his advice to the witness in instructing the witness not to take the oath?

Mr. RISEBERG. I am not prepared to lay out any detailed analysis of the basis for the conclusions.

Suffice it to say that one indication of that is the provision that I have already cited to you, and that is C-2 of the resolution that we have been discussing that refers to oaths being administered by the chairman or a member of committee, plus our basic view that the subpoena as issued is of doubtful legality.

Mr. FRANKEL. Mr. Michie.

Mr. MICHIE. Would you care to elaborate, Mr. Riseberg, on your doubt of the legality of the subpoena, please?

Mr. RISEBERG. I am not prepared to today, no.

Mr. MICHIE. You are not prepared to give the basis for that statement?

Mr. RISEBERG. I think that at least one basis is that, is the fact that, it refers to a sworn statement, and C-2 says that the oath is to be administered by a member of the committee. So that woud be one basis.

But I certainly am not committing the Department to any limits of that position. There may be, and there are, other good reasons.

Mr. MICHIE. This despite Mr. Frankel having cited the authority of local officials to administer the oath in a proceeding of this nature?

Mr. RISEBERG. Well, I think that the authorization—we are on Senate premises, and the Senate rules, or resolution, I think, clearly indicate who has authority to administer oaths, so that there is serious question about Mr. Sparks' authority, even assuming these rules are valid.

Mr. MICHIE. Mr. Frankel, do you have anything to add?

Mr. FRANKEL. Not today.

Mr. MICHIE. This deposition will be recessed.

This matter will be referred to the chairman for disposition. Until then, this deposition is in recess until further notice.

Thank you, gentlemen.

[Time noted, 10:57 a.m.]

WILLIAM S. COHEN, MAINE
LARRY PRESSLER, SOUTH DAKOTA
CHARLES E. GRASSLEY, IOWA
PETE WILSON, CALIFORNIA
JOHN W. WARNER, VIRGINIA
DANIEL J. EVANS, WASHINGTON
JEREMIAH DENTON, ALABAMA
DON NICKLES, OKLAHOMA
PAULA HAWKINS, FLORIDA

JOHN GLENN, OHIO
LAWTON CHILES, FLORIDA
JOHN MELCHER, MONTANA
DAVID PRYOR, ARKANSAS
BILL BRADLEY, NEW JERSEY
QUENTIN N. BURDICK, NORTH DAKOTA
CHRISTOPHER J. DODD, CONNECTICUT
J. BENNETT JOHNSTON, LOUISIANA
JEFF BINGAMAN, NEW MEXICO

STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

July 23, 1986

Honorable Otis R. Bowen, M.D.
Secretary,
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

As Chairman of the Special Committee on Aging, I am writing to share with you my deep concern and dismay over learning that department officials presented inaccurate and misleading testimony before the Committee at the March 6, 1986 hearing on the reuse of dialysis devices.

I recently learned of a memorandum prepared by John Marshall, Ph.D., Director, National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA), for Robert E. Windom, M.D., Assistant Secretary for Health. The memorandum, a copy of which I have enclosed, is based upon the NCHSR/HCTA's "Assessment of Medical Technology: Reuse of Hemodialysis Devices Labeled for Single Use Only" initiated in April 1986, following the Committee's March 6 hearing.

This alarming and shocking memorandum reveals all too clearly a severe breakdown in communications and coordination among the agencies responsible for the safety and well-being of dialysis patients: the National Institutes of Health (NIH); the Food and Drug Administration (FDA); the Health Care Financing Administration (HCFA); and the Centers for Disease Control (CDC). Indeed, as Dr. Marshall observed in his memorandum, these agencies "have had a long but non-productive involvement with [reuse] issues." Moreover, it confirms many of the serious concerns regarding the safety of reuse that were raised in the Committee's staff report as well as in testimony, but denied or dismissed by witnesses representing the Department of Health and Human Services (DHHS). The Marshall memorandum states, however, that the NCHSR/HCTA assessment "uncovered serious omissions and inaccuracies in the testimony."

The memorandum indicates that Dr. Marshall, the Department's principal witness at the March 6 hearing, was himself the victim of misinformation and lack of information regarding the safety and efficacy of dialysis device reprocessing and reuse. Further, the findings of the NCHSR/HCTA assessment serve as a strong indictment of failure on the part of those who were responsible for providing Dr. Marshall with accurate and complete information in preparation for his testimony.

The Marshall memorandum establishes that much of the information and data previously used to support the "safety" of reuse, such as the NIH report "Multiple Use of Hemodialyzers" (e.g., the Dean report), is unreliable.

I trust now that you can understand and appreciate why I continue to be deeply concerned for the health and safety of this nation's 80,000 dialysis patients, many of whom have falsely and wrongly been misled into believing that there are no risks associated with the reuse of their dialysis devices.

In light of the NCHSR/HCTA assessment findings and the most recent outbreaks of life-threatening bacterial infections in dialysis patients subjected to reuse, I strongly urge you to take immediate action on Dr. Marshall's recommendation:

> "The Public Health Service needs to take a clinically and scientifically based stand with respect to this issue. We need to communicate that directly and emphatically to the Health Care Financing Administration, even if that means recognizing that our earlier testimony was flawed."

In addition, and in the interest of adequately protecting dialysis patients from any further threat of harm and injury, I am requesting that you take immediate action on my earlier recommendations: (1) require dialysis clinics to adequately inform their patients of the risks of reuse and prohibit the clinics from coercing and forcing patients to reuse their dialysis devices; (2) withdraw HCFA's proposed regulations that would lower the dialysis reimbursement rate and, consequently, force still more clinics to reprocess and reuse dialysis devices; (3) conduct appropriate and controlled preclinical and clinical testing to determine the safety and efficacy of the reprocessing and reuse of dialysis devices; and (4) direct the FDA to impose its good manufacturing practice regulations on reprocessors of dialysis devices, and to develop uniform safety standards for the reprocessing and reuse of dialysis devices and supplies.

Should you or your staff have any questions regarding this request, please have your staff contact Jim Michie or David Schulke at 224-5364.

Thank you for your cooperation and assistance in this important matter.

Sincerely,

John Heinz

John Heinz,
Chairman

Enclosure

JH:jfm

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date JUL 8 1986

From Director, National Center for Health Services Research
and Health Care Technology Assessment

Subject Hemodialyzer Reuse

To Assistant Secretary for Health

ISSUE

As HCFA continues to ratchet down the reimbursement rate for hemodialysis, concern has grown on the part of hemodialysis patients and the Congress, with respect to the safety and efficacy of the reuse of dialysis equipment, including bloodlines, tubing, transducer caps, and filters. Senator Heinz was sharply critical of the Public Health Service's role in this process during hearings which he conducted on March 6 of this year. The involvement of NCHSR is only recent, but NIH, FDA and CDC have had a long but non-productive involvement with these issues. During the March 6 hearing, at which I was the witness for the PHS, accompanied by John Villforth of FDA, we agreed to do an assessment of the state-of-the-art. As events have unfolded, it is clear that the March 6 testimony was not based on all of the germane facts and that we may need to take a position counter to that which we argued on March 6. We need to ascertain a PHS position and inform HCFA of that position so as to minimize embarrassment for the Department.

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ACTION

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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

August 15, 1986

The Honorable Otis R. Bowen, M.D.
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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I am writing to share with you my recent findings concerning a grave injustice that is being done to Medicare's 80,000 dialysis patients who are threatened by recent actions within the Department of Health and Human Services.

The Aging Committee's ongoing investigation into reuse of disposable dialysis devices has revealed inexplicable and ill-conceived activities within the Public Health Service (PHS) and the Health Care Financing Administration (HCFA). Specifically, I am referring to the abrupt termination on August 6, 1986 of the assessment of reuse procedures by the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA), and HCFA's premature publication on August 15, 1986 of reductions in Medicare's dialysis reimbursement rates, which will become effective on October 1, 1986.

As you know, HCFA relies very heavily upon NCHSR/HCTA's scientific and technological expertise in developing and finalizing its actions regarding administration of health care financing. I must assume that such was the case in HCFA's decision this week to proceed with the dialysis reimbursement rate reductions. Further, I must assume that HCFA relied upon the NCHSR/HCTA's draft assessment report that was submitted to the Assistant Secretary for Health, Robert E. Windom, M.D., on August 6, 1986.

I deeply regret to inform you that the NCHSR/HCTA report is seriously flawed. The report lacks critically pertinent information concerning deaths, serious injuries, extremely poor reprocessing procedures in dialysis clinics, and numerous deficiencies in manufacturing practices of firms that market dialysis and reprocessing devices.

The Committee's investigation has determined that the NCHSR/HCTA staff was forced to hastily finalize the report in order to meet the August 6 "deadline." This, without their having had the time to review and consider reams of this very pertinent documentation, some of which Committee staff provided to NCHSR/HCTA on August 2 and August 10. Additional such materials were provided to NCHSR/HCTA by DHHS on August 11. It is my understanding that still more of this documentation has yet to be submitted by FDA to NCHSR/HCTA.

Assuming that HCFA relied upon the seriously deficient NCHSR/HCTA assessment report to make a final decision on the reimbursement rate reductions, one can only conclude that HCFA's decision process was flawed.

In light of these very distressing and shocking developments, I very strongly urge you again to take a personal interest in these matters which affect the safety and well-being of all dialysis patients. Specifically, I urge you to consider immediate withdrawal of the dialysis reimbursement reductions until NCHSR/HCTA has had sufficient time to evaluate the materials cited above for inclusion in its final assessment report and recommendations.

Thank you for your cooperation and assistance in this important matter.

Sincerely

John Heinz

JOHN HEINZ
Chairman

JH:jfm

UNITED STATES OF AMERICA

Congress of the United States

To Enrique D. Carter, M.D., Director, Office of Health Technology Assessment, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service, U.S. Department of Health and Human Services, Rockville, Maryland, **Greeting:**

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* August 26, *19*86, *at* ten *o'clock* a.*m., at their committee room* SD-G33 in the Dirksen Senate Office Building, *then and there to testify what you may know relative to the subject matters under consideration by said committee,* in sworn deposition to be conducted by committee staff.

Hereof fail not, *as you will answer your default under the pains and penalties in such cases made and provided.*

To James F. Michie, Chief Investigator *to serve and return.*

Given *under my hand, by order of the committee, this* 14th *day of* August, *in the year of our Lord one thousand nine hundred and* eighty-six.

John Heinz

Chairman, Committee on Aging

UNITED STATES OF AMERICA

Congress of the United States

Notice of
Senate Deposition

To Enrique D. Carter, M.D., Director, Office of Health Technology Assessment, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service, U.S. Department of Health and Human Services, Rockville, Maryland, **Greeting:**

Please *take notice that at* ten *o'clock* a.*m., on* August 26, *19*86, at Rm. SD-G33, Dirksen Senate Office Bldg., Washington, D.C., J.F. ~~*at*~~ Michie, D.G. Schulke & C.C. Jennings, *of the staff of the* Special *Committee on* Aging *of the Senate of the United States, will take your deposition on oral examination concerning what you may know relative to the subject matters under consideration by said* Special *Committee. The deposition will be taken before a notary public, or before some other officer authorized by local law to administer oaths; it will be taken pursuant to the* Special *Committee's rules, a copy of which are attached.*

Given *under my hand, by authority vested in me by the* Special *Committee, on* August 14, *19*86.

John Heinz

GPO [illegible]

JOHN HEINZ
Chairman

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

James S. Benson

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this 22nd day of September, 1986, and executed the above certificate in my presence.

Kay A. Levin
NOTARY PUBLIC IN AND FOR
State of Maryland
County of Montgomery

MY COMMISSION EXPIRES: July 1, 1990

WEDNESDAY, SEPTEMBER 3, 1986

Washington, DC.

Deposition of James S. Benson, called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 1:12 p.m., before Joyce Northwood, a notary public in and for the District of Columbia, when were present on behalf of the respective parties:

Appearances:

For the Special Committee on Aging:

James F. Michie, chief investigator; David Schulke, investigator; Christopher Jennings, professional staff member, Special Committee on Aging, U.S. Senate, room SDG-33, Dirksen Senate Office Building, Washington, DC 20510.

On behalf of the deponent:

Thomas Scarlett, Esq., chief counsel, Food and Drug Administration, room 6-57, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Mr. MICHIE. Good afternoon. My name is James Michie. I'm chief investigator for the Special Committee on Aging in the U.S. Senate. Present with me here in room SDG-31 in the Senate Dirksen Office Building is committee investigator David Schulke; committee staff member Christopher Jennings; Michael Davidson, Senate legal counsel; notary public and stenographer Joyce Northwood; and James S. Benson, Deputy Director of the Center for Devices and Radiological Health in the Food and Drug Administration, U.S. Public Health Service. Mr. Benson is accompanied by Tom Scarlett, general counsel for the Food and Drug Administration.

On August 20, Mr. Benson was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging for the purpose of being deposed by committee staff on this day of September, and that being September 3, 1986. A copy of the subpoena and notice of deposition will be made a part of this deposition record as exhibits 1 and 2 respectively.

Prior to being sworn in, Mr. Benson, I want to remind you that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury. Are you ready to proceed?

Mr. SCARLETT. Yes.

The WITNESS. Yes.

Mr. SCARLETT. I have a statement for the record.

Mr. MICHIE. We will recognize Mr. Scarlett. And you are representing Mr. Benson?

Mr. SCARLETT. I am. For the record, I am Tom Scarlett, chief counsel to the Food and Drug Administration. I have been designated by the Department of Health and Human Services to accompany James S. Benson to this interview.

The Department has asked me to indicate that it is volunteering to make Mr. Benson available in order to cooperate with the Senate Special Committee on Aging in connection with its dialyzer reuse investigation, and that Mr. Benson is participating in today's interview solely on that basis.

He has been advised by attorneys for the Department that the subpoena recently served upon him is of doubtful legality and that the Department does not regard his participation to be compelled by the subpoena or governed by its terms. Nevertheless, subject to this understanding, he is prepared to answer any questions you may have.

An issue has arisen at previous interviews as to the authority of the court reporter to administer the oath to witnesses. While the Department continues to believe that under the standing rules of the Senate only the chair or a member of the committee has authority to swear in a witness, in order to cooperate with the committee and avoid further delay to getting to the committee's substantive concerns, Mr. Benson has agreed to take the oath in question without conceding to it any legal significance it does not otherwise have.

In doing so Mr. Benson has also asked me to emphasize whether or not sworn he would answer truthfully to the best of his knowledge.

Mr. MICHIE. Is that your statement?

Mr. SCARLETT. That's it.

Mr. MICHIE. Once again, Mr. Benson, I want to remind you that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury.

Are you ready to proceed?

The WITNESS. I am.

Mr. MICHIE. Would the notary public please administer the oath to Mr. Benson.

Whereupon, James S. Benson was called for examination, and having been first duly sworn, was examined and testified as follows:

EXAMINATION BY THE CHIEF INVESTIGATOR FOR THE SPECIAL COMMITTEE ON AGING

By Mr. MICHIE.

Q. Would the witness state for the record his full name, age, and current home address.

A. James S. Benson, 47. My address is 1607 Mary Ellen Court, McLean, VA.

Q. With the exception of your having received appropriate and necessary advice from counsel, from your attorney regarding your rights as a witness in this deposition, has anyone prior to your appearance here today attempted in any way to influence your testimony in this deposition?

A. No.

Q. Prior to your appearance here today you were requested to bring with you your appointment calendars for 1986. Did you bring those with you today?

A. I did not.

Q. I want to share with you at this time two pieces of correspondence pertaining to the matters of concern in this committee's ongoing investigation into the reprocessing and reuse of dialysis devices. First we have a July 23, 1986, letter to Secretary Bowen from Senator Hinz, along with an attached memo dated July 8, 1986, to Assistant Secretary for Health, Dr. Robert Windom, from Dr. John Marshall, Director of the National Center for Health Services Research and Health Care Techology Assessment.

Have you seen this letter and attachment prior to your appearance here today?

A. Yes.

Q. Second, there's a letter dated August 15, 1986, to Secretary Bowen from Senator Heinz. Had you seen this letter prior to coming here today? Take your time please.

A. I'm aware of it. I think I've seen it.

Q. Are you a Public Health Service Officer?

A. I am not.

Q. Briefly, if you would, tell us what your academic background and training is please.

A. Academic background, bachelor of science in civil engineering, I have a master of science in nuclear engineering. That's the extent of my academic training.

Q. For the sake of saving time during this deposition, we will during the course of it refer to your agency as the FDA; the National Center for Health Services Research and Health Care Technology as the NCHSR; Center for Devices and Radiological Health as the Center; the Centers for Disease Control as CDC; National Institutes of Health as NIH; Health Care Financing Administration as HCFA; Public Health Services, PHS; and the Department of Health and Human Services as the Department. Is that acceptable to you?

A. Yes.

Q. Could you briefly describe for us the function and mission of your Center?

A. The Center's main function is to assure the safety and effectiveness of medical devices and safety of electronic radiological products. We have responsibility in the medical device area over certain products for premarket approval and over all products for postmarket surveillance.

I like to think of us as a problem-solving organization that conducts educational activities as well as research activities. I think in a nutshell that's the description.

Q. And what is your position at the Center?

A. I'm Deputy Director of the Center.

Q. For how long a time have you served in that position?

A. I think formally since 1983.

Q. What do you mean by formally?

A. I was Acting Deputy for roughly a year prior to that. So——

Q. So roughly in what month of 1982 did you become acting? Spring, fall, summer?

A. It was—fall maybe. I'm not sure.

Q. In the fall of 1982?

A. In the fall of 1982.

Q. Toward the end of 1982?

A. Yes.

Q. Would you describe briefly your function and responsibilities as Deputy Director? Take your time.

A. One primary responsibility is to serve in the absence of the Director. To the extent possible we share responsibilities. Often that's not possible. I feel responsible during the Director's absence for keeping the Commissioner informed on issues. I feel responsible for trying to maintain good management practices in the Center.

There are a number of responsibilities that we have that extend beyond the Center to FDA, chiefly, administrative kinds of things, that I also participate in. I serve, for example, as awards chairman for the FDA awards subcommittee, honor awards committee. That's the nature of the job.

Q. What is the number of personnel under your charge?

A. Approximately 750. That's not an exact count.

Q. Who is your immediate superior at the Center?

A. John Villforth is my immediate superior.

Q. For how long a time have your served under Mr. Villforth in your capacity as Deputy Director?

A. It would be since—I would say fall of 1982. But prior to that I was—I also served under him as Deputy Director for the Bureau of Radiological Health. And that dates back to 1976 I think.

Q. That's fine. How closely do you work with Mr. Villforth in fulfilling your daily tasks and responsibilities?

A. That varies greatly. Sometimes when we're crunched, not very closely at all, because we're going in separate directions. Other times I would say very closely. We try to attend our own Center staff meetings together, and I would say that would be the primary opportunity for working together.

Q. Does he delegate a great deal of authority to you in managing the more than 700 people in the Center?

A. I would say that John has his own style of delegation. In a way he delegates nothing. On the other hand he delegates a great deal. He never really relinquishes responsibility for things, yet I feel like I have a lot of responsibility. So that's not an area of controversy or anything.

Q. Who is Mr. Villforth's immediate superior?

A. The Commissioner of the Food and Drug Administration, Frank Young.

Q. In performing your duties as Deputy Director of the Center, how often do you receive instruction or assignments from Mr. Villforth for any particular task? Does that happen very often?

A. I'm sorry, oral instructions?

Q. No, no, no. How often do you receive instruction and assignment from Mr. Villforth in performing your duties? Does that happen very often? Or is it that he delegates a great deal of authority to you and that doesn't happen very often? I'm just trying to find out how closely he supervises you.

A. I would say that—if there's an issue that we're both aware of, you know, we've known each other long enough that we basically accommodate to a role. So there's not a great deal of oral instructions. I might say to him, John, I will handle this if that's OK with you. And he'll say fine.

There are other times when, if he's unavailable or knows he's going to be unavailable, he would more directly ask me to take responsibility for a given issue.

Q. As Deputy Director of the Center have you ever received from anyone else in the PHS chain of command above Mr. Villforth instructions or assignments in the performance of your duties and responsibilities?

A. Yes, yes.

Q. Who might that be?

A. I would—in terms of line authority, I would say either the Commissioner or the Deputy Commissioner I would receive instructions from. And again, the normal pathway there, would be if they had something they wanted to know or if they wanted something, they would normally call John first. In John's absence they would call me.

Q. Is it common practice in the performance of your job for you to communicate directly with the Commissioner?

A. I wouldn't say it's common practice. I try to keep—I feel responsible again in John's absence for keeping him informed on various issues. And in those instances I would either send him a note or call him, usually send a note on those cases.

Q. On those occasions when you do communicate directly with the Commissioner, do you always clear these communications through your superior, Mr. Villforth?

A. Most often not. Because it would be in his absence that I would be communicating.

Q. Does it ever happen though when Mr. Villforth is there or has it ever happened when he was present?

A. I'm sure it has. I can't—I don't recall a specific example.

Q. On those occasions, would you normally at least let Mr. Villforth know about your communicating with the Commissioner?

A. In general, yes, if he's gone for a long time and there was something verbal, you know, I probably—I'm apt to forget it. If it's in writing I would normally cc him or make sure that he had a copy of it.

Q. Do you ever on occasion communicate with the Commissioner in writing on a confidential basis or on a "for administrative use only" basis?

A. I would say that I've never communicated with him on a, quote, confidential basis. I'm not even sure I know what you mean by that. Also I'm not sure I know what you mean by——

Q. For example, have you on occasion, however seldom, sent the Commissioner notes or memos that were stamped or labeled as confidential or for administrative use only?

A. I don't recall ever having done that.

Q. Do you have a definite recollection of not having done it?

A. I don't want to—I don't know how to answer you, Jim. I don't recall ever doing that. I don't want to say I've never done it because I'm just not sure. But I don't recall ever having done it.

Q. On August 29 of this year the FDA provided me for review certain documents and other written materials that you and I discussed on the day that you were served with the subpoena for appearing here today. In addition to your appointment calendars and six or seven interoffice memorandums that were deposited in your electonic file, are there any other personal records that you may have kept, hand written records of telephone calls, meetings, logs, diaries, notebooks, or any other type of personal record pertaining to the issue of dialysis devices reuse or to the assessment of same by the NCHSR, records that you have not shared with this committee to date?

A. My instructions after our session on whatever date that was—what was it, the 29th?

Q. The 20th.

A. The 20th, was to work—with both my secretary and the young lady that sat with us, Janet Showalter, to make available through the appropriate channels the information you had requested. That included a folder that I kept on my desk. And I think I characterized that as something that I just kept handy and shoved things in as they came across my desk—that was a dialysis folder.

And to my knowledge 100 percent of that material went over to the Office of Legislative Affairs, which I understand you subsequently pursued and indicated what you wanted copies of and what you didn't. So to my knowledge—I made a conscientious attempt to collect 100 percent of the material that you had requested and—I mean not personally, but I asked my secretary to do that and Janet Showalter to do that.

Q. Have you been involved in any way in the FDA/PHS activities concerning the issue of reuse of disposal devices in general? Not just reuse in dialysis, we're talking about reuse of disposal devices in general?

A. Yes. I don't know what I would characterize as a PHS effort in that area. We have a reuse committee within the Center. If that's what you're talking about, then the answer to your question is yes.

Q. You are aware of the fact that there also has been interest at NIH as well as CDC?

A. Sure.

Q. As well as at NCHSR, you're aware of that; are you not?

A. Yes, yes, yes. I would say my involvement with PHS efforts in those areas is minimal. I know that when Cy Perry held a conference some years ago, I was involved in some of the early planning for that. I don't think I've had any interaction with people outside of the Center on nondialysis reuse. I've been in a few meetings internally over the past years which I couldn't—I'm not even sure I remember very well to tell you the truth.

Q. Have you been involved in any way in FDA/PHS activities specifically concerning the reprocessing and reuse of disposal dialysis devices?

A. Off and on I have; yes. I don't feel like I'm in the mainstream of those activities, but off and on; yes.

Q. Would it be accurate to suggest to you that you—although as you state you've been involved off and on, that you're aware of the various activities within the Center with regard to this issue?

A. Yes.

Q. Could you tell us for how long a time have you been involved in this specific issue?

A. Well, clearly not earlier than 1982 when the two bureaus merged. The first involvement that I recall—let me go back.

When we first merged we had a series of briefings from the Medical Device Bureau, the people from the Medical Device Bureau. I'm sure that dialysis was mentioned in there, but I don't recall it. The first incident that I recall was an incident of patient overheating in Dallas. And I think that was—I'm not sure of the date on that. We can look it up. And that was really my first involvement I would say with dialysis.

That was—I don't think—that was not a reuse issue but it was a dialysis issue. So I would say off and on ever since then.

Q. Did there come a time when your involvement increased? And if so, when was this, approximately when?

A. I don't know how to answer that. I would say that, you know, we had from time to time issues that came to the forefront, whether they were public health issues or not. Your committee took interest, then obviously we all got more interested. So I mean whether it's public health or whether it's outside interest, you know, that's going to perk up our interest. So——

Q. Specifically what was your involvement when the dialysis issue became perhaps more visible?

A. I don't know how to give you a good answer to that. I think again——

Q. Did you keep the Commissioner apprised of what was going on, for example?

A. Well, recently over the past, I would say several months I kept him apprised of some of the concern about disinfectant problems. If that's what you're referring to, then that would be an example of my informing him, or the Center informing him.

Q. Did you ever have any involvement at all, supervisory or otherwise, with the reuse committee that I believe consists of personnel within your Center?

A. That's right. I need to digress a second to answer that. Do you understand how those committees operate within the Center?

Q. Tell me how—what your understanding is.

A. OK. We have a series of committees, 20 in all, who have functions of planning or looking at what we call crosscutting issues. They have many purposes. Planning is obvious, some of the crosscutting issues are an opportunity to enable people from various segments of the Center to communicate with each other. I would say that's a prime function for some of the crosscutting committees.

The reuse committee is one such committee. Some time ago that committee was given a charge to come up with a policy for reuse.

Q. Do you remember when?

A. A long time. I don't remember when. But I would think a couple 3 years anyway. It's been a long time. As that committee got closer to coming up with the document, I think I personally would have paid more attention to what they were doing. But in terms of—the reason for the digression, I wanted to explain the, quote, supervisory role.

I don't think I supervised these committees in the sense of a normal—the way a normal employee would be supervised. The committee exists mainly as an opportunity for people to talk to each other. And in that sense then I would be involved with all 20 committees, not assigned supervisory responsibility, I would say perhaps a management responsibility.

Primarily they report—if you want to put it—well, they don't report to anybody, but they're under our office of management and services in the sense of administrative care and feeding. All of the people in those committees are in various offices and have supervisors.

Q. Do you recall there having been formed within the FDA a dialysis use committee in time prior to October 1984?

A. Is that the—is that the document you showed me? If it is, I mean—I really don't recall that. But I know of its existence, I know what you're talking about.

Q. What I'm trying to get at—we'll get to the document in a moment, Mr. Benson. What I'm trying to get as is, in addition to the reuse committee, was there a separate committee called the dialysis use committee?

A. I'm aware of a committee that was set up some time ago, and I presume that was the name of it, probably was the name of it.

Q. What purpose—for what purpose was this set up? Can you recall?

A. I think I can answer your question but only because I reviewed that document last night and because I talked to someone this morning about how it came to be. I really don't recall from memory at the time how it was—how it was set up and why it was set up.

Q. Do you recall who were members of this dialysis use committee as differentiated from the reuse committee?

A. Well, I know William Dierksheide chaired it. I don't recall—I mean I remember that again from looking at the document. I don't recall the other people. I think their names are in there as a matter of fact.

Q. To whom did this dialysis use committee report?

A. As I understand it, it was created by the Office of Training and Assistance. And it was a committee that reported to—I don't know, the Director or Deputy Director of that office at the time, and was made up of people from across the board in the Center—in other words, people outside of that organization.

Q. I have here a copy of the minutes, at least most of the minutes, of the reuse committee here, the first being dated September 7, 1983. It memorializes the fact that this committee held its first meeting on Tuesday, August 30, 1983. It goes on to say that "the main purpose of the meeting was to discuss the responsibilities and aims of the committee."

And if you would pass that to Mr. Benson so that you can look at that, that first set of minutes.

Now, does that first set of minutes refresh your memory on which came first, the reuse committee or dialysis use committee?

A. Well, if you have the document there, it would be easy to look up the answer to the question. I really don't recall.

Q. You do not recall?

A. I do not recall.

Q. Would it be accurate to say that, since the dialysis use committee report bears the date of August 23, 1984, that these two committees were operating simultaneously?

A. Yeah.

Q. Do you have an explanation for that?

A. As I understand it, the original charge to the reuse committee, which was pretty much self-generated, originally excluded dialysis. They were looking at reuse issues across the board. And what I tried to piece together this morning, as a matter of fact, was the history of the other group because I didn't recall it.

Q. Why did you try to do that this morning, Mr. Benson?

A. Because I was coming down this afternoon. I wanted to be reasonably well informed.

I had personally been very concerned as a result of the patient overheating problem. And that was really my first introduction to dialysis. And I think I had asked our Office of Training and Assistance—which is comprised of almost all nonmedical device people—they were from the Bureau of Radiological Health—to try to get themselves up to speed.

Because at the time I suspected that a lot of the dialysis problems were of a nature that were similar to the problems that we had tackled in radiology, that is to say that, you know, you needed to have more than equipment operating properly, you needed to have people operating that equipment properly.

And I suspected that this was part of the problem, and asked that they try and pursue it. And I think that was at least in part of the genesis of that Dierksheide committee if you will, I forget the name.

Q. Was this committee one of the 20 or so that you mentioned?

A. No, it was not. It was strictly done within the Office of Training. Even though it had people across the board on it, it was not 1 of the 20.

Q. Would it be accurate to call it an ad hoc committee?

A. Sure.

Q. To your knowledge did this committee maintain minutes of all of its meetings?

A. I don't know.

Q. Are you a member of the senior staff of the Center?

A. Yes.

Q. Do you recall Dr. William Dierksheide—am I pronouncing that correctly?

A. I think so. Dierksheide.

Q. D as in David I-E-R-K, S as in Sam, H-E-I, D David, E, Dierksheide.

Do you remember him having forwarded to the senior staff, which of course would have included you, on October 23, the dialysis use committee report, this report that I have here? And I'll share it with you now. Do you remember that?

A. I do not remember that.

Q. Do you remember ever discussing with Dr. Dierksheide any aspects of this committee's work and also the production of this report?

A. I don't.

Q. What was Dr. Dierksheide's position at the time of the dialysis use committee's existence? Do you recall?

A. He would have been a fairly recent detailee or person—but a fairly new member of the Office of Training and Assistance. If you looked up the job record I'm not sure what it would have shown. But he was sitting in that group at that time.

Q. Is he still at the Center?

A. Yes, he is.

Q. Now, you stated a moment ago that you don't recall reading this report?

A. What I said was I didn't remember receiving it at the time that it was issued.

Q. Do you recall having been briefed about it?

A. No, I don't. I really don't.

Q. Do you recall—do you have any recollection whatsoever of anyone having passed on to you the contents of that report at that time?

A. Well, I'm sure some of the information that's contained, the problems that are laid out, things like that, were described. So I don't want to say that I had no knowledge of the content. But I don't recall the report per se.

Q. But you don't have—correct me if I'm wrong, but you don't have a definite recollection of not having received this report?

A. I would also answer yes to that. I'm just not sure.

Q. In other words, it's possible that you did, but you just don't recall?

A. Yes, it's possible. The fact that it's addressed to me makes me think that I probably—that I might have gotten it. But I just don't remember.

Q. Did you review this report today prior to your appearance here?

A. I scanned it last night.

Q. Last night?

A. Last night.

Q. How did you obtain a copy of this report yesterday?

A. It was—well, literally I got it from Bob Eccleston. He had pulled together materials. I had left town soon after you were out, so I didn't really know what they had sent over to OLI for you to look at. So he had pulled together that material for me. And this was one of the elements—I think this was one of the elements that he had sent on over.

Q. So last night you reviewed the documents that I had culled from the stack of documents that were provided to me for review; is that correct?

A. Well, what I asked for was—and what I felt I should get on top of was any document that I had signed off on or had been addressed to me. I was trying to familiarize myself with things that I felt I should be aware of. So I don't know what category this fit in.

It could have been simply that it was addressed to senior staff and Bob pulled it for that reason or because it was in the package to you, either one.

Q. Now, having had your memory refreshed at least insofar as the existence of this report is concerned and having read it last evening, I'll ask you to search your memory and tell us if reading that report jogged your memory, and in so doing do you recall that the report recommended that the dialysis system investigations contracts, RFP 223-84-4276, be designed to address user-related problems listed in that report? Do you recall that?

A. I'm not sure what the reference is. Can you get me in there and let me look at that.

Q. Well, you have the document, Mr. Benson. I think you'll find that on the front page, the cover memo. Now, let's look on into the body of the report. Here we have recommendations.

Does that refresh your memory as to any activity you might have been involved in back in 1984?

A. Let me read the paragraph.

It doesn't refresh me. I think they may be talking about what we call the State contracts. If it's those, then yes, it does. If it's not, then I don't know what it refers to.

Q. You do believe that the contracts addressed in that particular report are those that were recently completed for the FDA by the States of California, Massachusetts, Ohio, and the District of Columbia?

A. I'm guessing that that's what he's referring to. I don't recognize the numbers.

Q. These contracts that were recently completed for the three States and the District of Columbia——

A. I think one's still in draft form, but three are complete if I recall. I think that's right.

Q. The work, though, itself has been completed?

A. Yes.

Q. Isn't that correct?

A. Yes. Well, the interviews and whatnot, yes.

Q. Have you read any or all of those reports?

A. I have not read any of the reports at all, no.

Q. So as a result, you don't know what's in them?

A. I have—I've discussed them briefly. I have a general sense of what's in them.

Q. You've been informed of what the findings were?

A. In a general way, yes.

Q. By whom?

A. By—let's see, I discussed it with Mr. Eccleston, I think to a limited extent with Mr Arcarese who is Director of the Office of Training and Assistance.

Q. Anyone else?

A. Probably. I'm not sure. I may have discussed them in the past with Larry Kobren, who's the project officer, I think, for all four contracts.

Q. What about Dr. Villarroel?

A. I don't believe I've discussed them, at least not recently—I don't remember discussing them at all with him.

Q. Have you discussed the findings with anyone at the NCHSR?

A. I had a discussion with John Marshall, I don't know, 3 weeks ago or so. Later in that discussion I'm sure that the State contracts were discussed, but not in depth, not—as one of the elements of the whole—I mean it was mentioned that State contracts did exist. They're trying to look at what goes on in dialysis centers, as opposed to let's try to review the contracts and really lay out what the findings were.

Q. To your knowledge did these surveys, as you have been informed of the contents, reveal many user related problems included problems associated with reprocessing dialysis devices, problems of quality control, contaminated water, and poor reprocessing producers that could lead to patient injury and life-threatening circumstances? Have you been informed of that?

A. That's my general understanding, that those kinds of problems have been identified, yes.

Q. Getting back to the dialysis use committee report of October 23, 1984, do you recall it having stated, that, quote: "Installation of proper water treatment system is utmost"—word utmost underlined—"importance to protect the health of dialysis patients"? And if you wish, you may refer to the document. I think you'll find that on page. 3.

A. Well, I believe you.

Q. I'm not certain though.

A. Yes, it is.

Q. And is the word "utmost" underlined, underscored, or is that my emphasis?

A. It's not underscored here.

Q. Then it's my emphasis. Do you recall that among the attachments to this report—and of course we're referring to your having read this document yesterday—that there were 39 pages of user-related problems and elaborations including accidents, injuries, malfunctions, potential and serious hazards associated with dialysis and the reprocessing and reuse of disposable devices, poor quality control, bacterial contamination of these devices, and the water used in reprocessing?

A. I scanned the report last night, and I didn't read through all the attachments. But yes, I am aware that those attachments are there and they describe those kinds of problems.

Q. Can you tell us where—how did FDA come into the information that is appended to this report? Where did this information come from?

A. I think most of it, perhaps all of it, came from our DEN, device evaluation network I believe it stands for, which is a voluntary reporting system that's been in existence for quite some time, since before I was part of the Center. I think, if not all, most of those reports came from there.

Q. But you're not certain that all of it did?

A. No, I'm not certain.

Q. Do you know where some might have come from?

A. Well, this predated the MDR regulation, so I presume that it was from DEN. I think they got hold of whatever—as I understand their charge, it was to try to find out what kind of problems existed. And they were trying to get data from wherever they could. Some of it may have come from the literature. I really am not sure.

Q. Is it possible that some may have come from the CDC?

A. Yes, certainly.

Q. Is it likely that some came from the CDC?

A. I really don't know.

Q. To your knowledge was this report dated October 23, 1984, ever shared with the members of the reuse committee?

A. I don't know. But I'm sure it must have been, should have been. I think that much of the people—there should have been a great deal of overlap with the people on the two committees.

Q. In fact there was; was there not?

A. I'm just looking now to see.

Q. Mr. Kobren's name appears on the minutes of the reuse committee and I think his name is there on that report, is it not? Do you recognize anyone else?

A. Well, Fernado Villarroel I'm sure was on both, should be, Villforth may be, I don't know. I'm sure it was shared. I mean I can't believe it wouldn't have been shared.

Q. To your knowledge was this report ever shared with anyone outside of your center prior to my having reviewed it on August 29?

A. I don't know the answer to that.

Q. Do you know whether or not it was ever shared with the Commissioner?

A. Do not know. Probably not.

Q. Was Mr. Villforth aware of this report at the time?

A. I don't know the answer to that.

Q. If you want to add something, lease.

A. No, no, that's all right.

Q. In light of the contents of this report, would you think it likely that Mr. Villforth would indeed have been informed of this report and at least in a summary way given some idea as to what the findings of this committee were?

A. I don't want to mince words with you. I think that we both are aware of the kinds of problems that exist in dialysis centers. It's a concern, it's a long-standing concern.

Q. No, I understnd that, Mr. Benson. But I'm trying to get you to focus on that particular period in time.

A. OK, all right. Re-ask the question.

Q. The question is simply this. Because of the contents of this report, as I described earlier and as you read last night in order to refresh your memory, do you think it likely that this report, the findings of this report, at least in a summary way, would have been conveyed to Mr. Villforth upon completion of that report?

A. Yes, I would expect there would be, I don't have knowledge of that, but I would expect that there would be.

Q. Do you think it's possible that, although you have no recollection at this time, that you may very well have attended a meeting or discussion with Mr. Villforth or may have been a party to a discussion with Mr. Villforth concerning this report?

A. It's possible. It's—I mean if such a meeting would have happended, I would have—and I'd have been available, I would have attended—I would have wanted to have attended. But I don't recall attending such a meeting.

Q. Do you recall what happened as a result of this report? Was there any action? Were there any directives given?

A. The evolution, as I learned this morning, was that Arcarese was not satisfied with this report and felt that it was merely a collection of anecodotal data, that it really didn't characterize what went on in dialysis centers, and it was for that reason——

Q. How could he have been sure of that?

A. I'm not sure he was sure. I don't know that he was sure. I'm telling you what his reaction was as he talked to me this morning.

Q. But my question to you though, if I may interrupt you for a second, is how could he have known what was happening or what reality was like in dialysis clinics when in fact the FDA does not inspect these clinics, No. 1; and No. 2, the reporting system at FDA is voluntary?

A. I think that's a valid point, the same point I was making. He was unsure of the validity of this report, whether this was the sum total of how many incidents are reported here. I'd say personally——

Q. Or whether it was the tip of the iceberg?

A. Exactly. And the State contracts were let in an attempt to get a better handle—I mean we operate under pretty limited resources. The State contracts were a way of trying to get—if not good soundings of that iceberg—at least an idea of the depth of it. I think that's a good way to characterize it.

Q. And did they not?

A. Yes; I think so.

Q. To your knowledge did your Center at any time prior to or during the NCHSR assessment of dialysis device reuse share the dialysis use committee report with anyone at the NCHSR?

A. I don't know; don't know.

Q. Do you think it should have been shared?

A. I think because of the scrutiny that you are putting on the dialysis issues, that it should have been shared for that reason alone. As far as valid scieintific information, I'm not so sure that it added—it would add that much. If I could make a retrospective judgment, I would have said definitely shared, regardless of your scrutiny.

Q. In addition though to your observation that it should have been shared because of this committee's scrutiny——

A. Or without it, either way.

Q. I understand. Would you also—would you also wish to state that it should have been shared, perhaps even the main reason being that the NCHSR was in the process of conducting an assessment of this very issue? Would not that also have been a reason for the FDA to share this with NCHSR? Would that have been a valid reason to transmit this report to NCHSR?

A. The answer to your question is yes, but I'd like to make an additional statement about that. The fact is that this report, as I understand it, was not considered very valuable and——

Q. By whom?

A. By Mr. Arcarese. He's the only one I discussed it with, so let me limit it to him. I think though—I can't make a supposition. I think it would have been very easy to have not bothered simply for that reason alone. I'm trying to explain to you why—I don't know whether it was or not. But if it wasn't, that may have been the reason. That's the reason I'm presuming.

Q. To your knowledge, did your Center share this report with the House Ways and Means Subcommittee on Health which at that time, during the production of that report, had an interest in this very same issue, that is, the safety and efficacy of reuse?

A. I don't know; don't know.

Q. Do you recall that—of course you have the document in front of you to see for yourself, Dr. Dierksheide's cover memo transmitting the dialysis use committee report to the Center senior staff, a statement in there, quote:

> This document is for internal planning purposes only. Because of its findings being inconclusive the Committee asks that the report not be distributed outside the Center.

A. Yes, I recall seeing that.

Q. Could this request to the committee possibly explain why this report may not have been shared with the NCHSR, the Commissioner, or the House Ways and Means Subcommittee on Health, or Senate Committee on Aging prior to its March 1986 hearing? Is that the explanation?

A. It's certainly a good literal explanation. In truth I don't believe this is the reason. I think that statement is simply a statement of, this is a preliminary thing, I as the author haven't had it fully reviewed, or I don't have confidence in it, and I don't want it to be seen as a final document. That's how I interpreted that statement. But taking the words literally, then the answer to your question is yes.

Q. It you could—some time over the next week or so, could you try to determine as a courtesy to the chairman of this committee whether or not that report was shared with the House Ways and Means Subcommittee on Health.

A. Let me make a note.

Mr. SCARLETT. For the record, we'll pass the request on to Mr. Docksai.

The WITNESS. Wait a minute--go ahead. And what was the committee again?

Mr. MICHIE. House Ways and Means Subcommittee on Health.

By Mr. MICHIE.

Q. Did you or to your knowledge did anyone else within your Center, the FDA, or within the PHS make a conscious decision to not share the October 23, 1984, dialysis use committee report with the Senate Committee on Aging prior to the committee's March 6, 1986, hearing?

A. Now, which report was that? Same one again?

Q. Correct.

A. Not to my knowledge. I certainly did not make a conscious decision of that nature. And to my knowledge no one did. I should add though, I did not—I was not—really at all involved in the preparations for that hearing. So I really don't know what went on.

Q. My reason for asking that question is that Senator Heinz on November 25, 1985, requested from the FDA any and all reports pertaining to this issue. Of course, on November 25, 1985, this October 23, 1984, report was in existence and reposited in your files at the Center?

A. Sure.

Q. That's why I ask this question.

A. I Just thought of something. Was not the request based on reuse issues?

Q. It was based upon reprocessing and reuse.

A. The thrust of this report was——

Q. Safety and efficacy?

A. Across the board, which would include but not be limited to. That may—if it was not —I don't even know if he had it in that background. It if was that's a possible explanation.

Q. Are you aware that Senator Heinz, chairman of this committee, invited Commissioner Young to testify on the March 6 hearing?

A. I know there were a number of letters. I don't have specific knowledge, but I think I know that or I knew that somebody was invited.

Q. Did you not see the letter of invitation to the Commissioner from Seantor Heinz?

A. I don't remember. I probably did. I don't doubt that one exists. You don't need to——

Q. I'm just wondering if you have a specific, definite recollection of Senator Heinz back in February inviting the Commissioner to testify at the hearing on March 6?

A. I don't remember an invitation to the Commission per se. I'm certainly aware that there was a hearing and that FDA was expected to testify.

Q. I have here for your reference a copy of the Chairman's letter to the Commissioner, February 21, 1986.

Mr. SCARLETT. Is there a question on the table,

Mr. MICHIE. I'm waiting for the deponent to familiarize himself with the letter.

By Mr. MICHIE.

Q. Does that refresh your memory? Do you recall seeing that letter?

A. I'm sure I did.

Q. During the days immediately following receipt of this letter, were preparations initiated within FDA and your Center for the Commissioner's testimony?

A. Well, I presume this letter or the knowledge that you were going to hold a hearing at which somebody from FDA would testify, you know, started a flurry of activity. So we were gearing up for a hearing. Whether it was with—I don't remember at the time whether we expected the Commissioner to testify or someone else. I don't recall.

Q. Regardless of that, were you involved in any way in this preparation?

A. I would say minimally, minimally involved.

Q. How were you involved?

A. I recall a meeting with the Commissioner a few days before the hearing where he wanted to know what was happening, you know, just wanted to get the lay of the land. I don't recall at that time whether a decision had been made as to who would testify from FDA or whether anyone from FDA would testify. I'm not saying a decision hadn't been made. I just don't know. I have specific recollection of that session.

I may well have been involved in other sessions, but not in the bulk of the work and the discussions. Much activity went on between our Center, people in our Center, and Dr. Marshall's folks in terms of gearing up for the hearing.

Q. Who in your Center would have been involved with preparations for the Commissioner's testimony?

A. I don't know whose testimony they were preparing for but——

Q. On the 29th of this month I reviewed a number of materials over at FDA, and prior to that over at NCHSR, and there was indeed a briefing book prepared for the Commissioner, I'm assuming by personnel within your Center simply, because it's your issue. It was a rather thick briefing book.

Do you recall such a briefing book?

A. I don't doubt that a briefing book was produced.

Q. But you had nothing to do with it?

A. No; I didn't have anything to do with it. You mentioned it when you came out a couple of weeks ago, whenever it was. At that time—I mean, I acknowledge the existence of a briefing book. Whenever there's a hearing we usually put a briefing book together.

At that time we probably assumed that either the Commissioner would testify of Villforth would testify and we needed to get them up to speed. That's the purpose of the briefing book, simply pulling together materials that exist. I didn't participate at all in the preparation for that hearing book so I'm really not at all familiar with it. I didn't review it. I don't know that I ever actually saw it.

Q. Do you know who did review it and do you know who was responsible for that briefing book?

A. Yes.

Q. Who was that?

A. Bob Eccleston would have been the primary person within the Center to pull that kind of material together. And I'm virtually positive that he did this one. Other people would have participated.

Q. And who might they have been?

A. Well, I know that Kobren, Larry Kobren, and Fernando Villarroel participated in pulling materials together or trying to, you know, get on top of issues. I remember them being in the immediate office. There were probably others. I don't know.

Pick anybody that had anything to do with dialysis in the Center. It's not unlikely that Ecckleston would have contacted them.

Q. Now, do you have—do you recall whether the decision was made, or hearing from someone that a decision was made, that the Commissioner would not be testifying at the March 6 hearing?

A. My recollection is that we were uncertain prior to the hearing who would testify. I recall a decision being made that John Marshall would be the lead person from the Public Health Service——

Q. From whom did you learn this? Would it have been Bob Eccleston?

A. I would have been Eccleston or Villforth probably.

Q. Is Mr. Eccleston immediately below you or are there several layers between the two of you?

A. Bob is within the small group of people in the office of the Center Director. So I would say he's just one level below.

Q. So he's fairly close to you?

A. Yes.

Q. Would it be accurate to say that if anyone would have briefed you on this decision he would probably have been the person?

A. Yes.

Q. Do you have a recollection of that briefing?

A. It wouldn't have been a formal briefing. It would have been maybe a hallway conversation. Or if he learned something that—for example, if he learned that Marshall was going to be the person testifying, he may have walked over and told me. It would have been that kind of conversation.

Q. Do you have a specific definite recollection of that happening?

A. No, I do not.

Q. You don't?

A. I do not.

Q. Do you know whether or not anyone in the Center, in your Center, advised the Commissioner not to testify at the March 6 hearing? Or anyone else anywhere in FDA for the matter,

A. I don't have a specific recollection of that.

Q. Do you have a faint recollection of something?

A. It wouldn't surprise me—let me phrase it this way.

Q. Go ahead.

A. It wouldn't surprise me for Villforth to have said to the Commissioner it's more work to prepare you for one of these things, let me do it. I mean that's typical of John. So I'm sure I've heard him say that is the past. Whether he said it on this one in particular, I don't know. But it was more of a tongue in cheek kind of statement where he's saying don't put us through the agony of getting you up to speed kind of thing. That's as close as I can come.

Q. As it turned out Mr. Villforth did not testify?

A. Well, he was a backup witness, as I recall.

Q. Yes; but he was not the PHS witness?

A. He was not the lead witness.

Q. And he did not offer written prepared testimony for the record; is that correct?

A. As far as—yes, I'm sure—well—yes, that's correct.

Q. Do you know whether or not anyone at the Center prior to the decision to have Dr. Marshall represent the Public Health Service drafted any testimony at all that would have been delivered either by the Commissioner or by Mr. Villforth?

A. I don't know for certain. It's certainly possible, especially if there was a lot of uncertainty about who would testify. Eccleston again in very energetic, he's a very conscientious person. He would have said, well, if there's a small chance I can get ahead of this and start drafting testimony, it's very possible.

Q. Did you at any time following the March 6 hearing review the briefing book or any papers contained therein that was put together by FDA?

A. I don't remember sitting down with that briefing book. I mean I'm sure I reviewed papers that were in it because it's a collection of materials. So I mean I'm sure I've seen them. But I don't remember sitting down with the briefing book per se.

Q. Is it possible then, perhaps even likely, that although you didn't have the responsibility for reveiwing the briefing book in its—in toto, that you might very well have reviewed certain documents that were put into that briefing book prior to the March 6 hearing?

A. Well, I don't—I don't—know, I don't think so. It's possible, but I don't recall having done that. I thought you meant afterwards had I looked at it.

Q. But now——

A. You're switching to before?

Q. Correct.

A. It's possible, but I don't recall.

Q. To your knowledge when and by whom was the decision made to have Dr. Marshall as a principal witness at the March 6 hearing?

A. I really don't know. I presume it would have been the Assistant Secretary for Health or—I don't know, legislative affairs person somewhere, I don't know.

Q. Did anyone not ever inform you of this?

A. Not that I'm aware of. You mean as to who made the decision? Not that I'm aware of.

Q. Do you recall when the decision was made?

A. Only that it seemed like it was close to the hearing. I don't recall.

Q. Close, within days?

A. It seems like it.

Q. Two days, a week, do you remember?

A. No, I don't remember. The only thing I remember is it was certainly down close to the time of the hearing.

Q. Do you know why Dr. Marshall was chosen to represent PHS?

A. No, I really don't. He does have a position with the health care technology assessment group that crosses all the agencies that would have had potential input to the session. So it was a logical choose in that sense. But other than that, I don't know.

Q. Are you aware that prior to April of this year, that the NCHSR had never performed an assessment for HCFA or anyone else in the Public Health Service or in the Department concerning safety and efficacy of reuse and reprocessing? Are you aware of that?

A. No, I'm not aware of it. I had never thought about it.

Q. Now, this briefing book that was put together at FDA, this briefing book was passed on to Dr. Marshall. Do you have any knowledge of that?

A. Presume—no, I don't. I mean I'm sure it's logical that it would have been. It would have been a courteous thing to do. I presume it was.

Q. To your knowledge have you—forgive me, I'm trying to—earlier you did state, did you not, that you have never reviewed this briefing book either before or after the hearing?

A. I think what I said was——

Q. You didn't recall?

A. I didn't recall having reviewed it.

Q. To your knowledge, was the October 23, 1984, report of the Dialysis Use Committee included in the briefing book that was prepared by FDA and passed on to Dr. Marshall?

A. If I were preparing the briefing book, I would have included it. So I presume it was in there. I don't know.

Q. Prior to his testimony on March 7, did you or to your knowledge did anyone else within the Center assist Dr. Marshall and his staff in drafting his testimony?

A. Well—there was a lot of support for Dr. Marshall. And I presume that included helping draft testimony, although I don't know that Eccleston and others were actually over at his building there and working with him and his staff.

Q. So thay did meet with him to brief him?

A. I'm sure he did, yes.

Q. Do you know what the content of these briefings might have been?

A. No, I don't know.

Q. Did Dr. Marshall ever consult with you directly concerning his testimony prior to March 6?

A. I don't recall any conversation with him on the testimony. I know that I did initiate a call or I wrote a note to him at one point, I don't remember the date of that, concerning CDC's MMWR article that was coming out. If that was prior to the testimony, then that might fit your question. But that's the only conversation I remember.

I mean that was the only interaction—I've has subsequent interactions with him, but they've all been since the hearing.

Q. Prior to the March 6 hearing, did you or to your knowledge did anyone else within your Center or elsewhere within FDA inform Dr. Marshall of the FDA's information as the regulator of medical devices regarding the reprocessing and reuse of disposable dialysis devices? Did you or anyone in your sphere or elsewhere in the FDA present the FDA's position regarding this matter of reprocessing and reuse of disposable dialysis devices?

A. Prior to the hearing?

Q. Prior to the hearing?

A. Well, I'm sure—I did not, to answer part of your question. But it would have been logical that in preparing him for the hearing that we would have briefed him on our position. I'm certain we must have.

Q. Do you know what that position was at that time?

A. It has changed; hasn't it? The position on what? Let me focus——

Q. The position on the issue of safety and efficacy of reprocessing and reuse of disposable dialysis devices?

A. Yes, I think I know our position—knew our position.

Q. What was it at that time?

A. Simply that reprocessing if done properly is as safe as single use.

Q. Anything else?

A. Well, I'm not trying to give you a full statement. I'm answering as best I can off the top of my head. I think that would have been our position on reuse. I mean certainly——

Q. That was the bottom line so to speak on the FDA's position at that time?

A. Yes.

Q. Prior to the March 6 hearing, did anyone to your knowledge within the Center or elsewhere within FDA, including yourself of course, inform Dr. Marshall or anyone on his staff that FDA was opposed to regulation or inspecting dialysis clinics because these activities would require additional and substantial resources which were not and are still not available?

A. I don't know or I can't recall any specific missile that would have so informed him. But it certainly was our position and I would have thought that he would have been informed of that. I wouldn't characterize it quite as you did by——

Q. Please, characterize it as you would.

A. Well, I think the concern has been—well, state it again.

Q. I'll repeat the question.

A. OK, that would help.

Mr. Michie. Could you read back the question please.

[The record was read.]

The Witness. I don't recall—I didn't so inform him. I don't recall anyone specifically informing him. Without being literal, I think that was our position in that there's longstanding concern about—we certainly well know that the Senator has favored GMP inspections within dialysis clinics and we've considered that and thought about it, maybe even before the Senator has, I don't know. It's been a longstanding issue.

There's no question in my mind that the clinical practice, the technology that's practiced in dialysis centers, could be improved, and if it were improved, patients would be better off. No question in may mind about that. How to achieve that, there is some question about.

And we have not been supportive of a straight—good manufacturing practices type inspection regulation, if you will for dialysis centers, both because of the interference and the concern that I think it would stir up within clinical medicine, as well as the costs that it would incur. I don't think it's a cost effective way of accomplishing the job that needs to be accomplished.

So in that sense, then that would have been the message that we should have given Marshall. And I would have expected we would have given Marshall—I would have given it to Marshall had he asked me, let me put it that way.

Q. Prior to the hearing did anyone within your Center or FDA including yourself assure Dr. Marshall that ample experience exists today to suggest that no health hazards for dialysis device reuse had been demonstrated?

A. Do it again, sir.

Q. Prior to the hearing, did anyone to your knowledge within your Center or anywhere else within FDA including yourself Dr. Marshall or anyone on his staff that ample experience exists today to suggest that no health hazards for dialysis device reuse have been demonstrated?

A. I'm not aware of anyone saying that to Marshall, saying that to anyone. I mean no, I'm not aware of that.

Q. Well, is it possible, is it plausible, that someone on your staff could have said this? Or do you find this statement to be repulsive in some way?

A. Well, the literal answer to your question is anything's possible. Repulsive is a strong word. I don't agree with the statement.

Q. So, in other words, at that time prior to the hearing, is it your belief that the FDA did not believe that there was ample experience in existence at that time to suggest that no health hazards for dialyzer reuse had been demonstrated?

A. You're getting me mixed up with double negatives here. I believe that in my own mind and in the minds of other people in management that should have knowledge of this area at FDA, at the time, felt that reuse was a potential problem, but that as a stand alone element of dialysis that it was not a major problem. It's certainly something that should be dealt with, it should be done properly, you know.

But I can't say—you know, almost any aspect of dialysis is a potential problem if it isn't done right and done carefully. Reuse certainly fits in that category.

Q. Let me share with you a copy of Dr. Marshall's prepared statement for the March 6 hearing. You'll find that on the last page of his testimony, very last page, he states quote, "Mr. Chairman"——

A. Wait a minute——

Q. Down toward the middle of the last page.

A. Next to the last page?

Q. Yes, next to the last page.

"Mr. Chairman, we consider that ample experience exists today to suggest that no health hazards for dialyzer reuse has been demonstrated."

My question to you is do you know what was the basis for this statement by Dr. Marshall?

A. Well, I would't have phrased it that way. I would have phrased it to say that we don't consider reuse to be a public health concern or something of that nature. So I don't know what the basis of this statement was.

Q. Do you think that statement is too strong a statement? Is that what you're suggesting?

Mr. SCARLETT. For the record, I think the witness should have an opportunity to review the testimony in full so as to get the context.

The WITNESS. Good point. Shall I do that?

Mr. MICHIE. You may do it afterward. Let's move on to the next question.

The WITNESS. Well——

By Mr. MICHIE.

Q. Is it possible that Dr. Marshall may have based this conclusion on the materials in the briefing book provided to him by FDA in preparation for his testimony?

A. As I said before, anything's possible. I don't think it's likely.

Q. The reason why I chose that statement is you can see it's conclusory and it is toward the end of his statement, a summation of his statement.

A. Excuse me a minute. OK.

Q. As an example, we have a copy of an 8-page briefing paper that was included in the briefing book that was passed on to Dr. Marshall by personnel in your center. It's titled "Briefing on the

Reuse of Hemodialysis System," which was prepared for Commissioner Young initially.

A. Uh-huh.

Q. Where you involved in any way in the draftng or review of this briefing paper?

A. As I recall, I attended this briefing and I think represented the center. I think John Villforth was not there for this, and probably worked with the people as I would usually do in terms of preparing the briefing materials, just kind of gettng them up to the speed.

Q. Do you recognize this document?

A. Yes, I do. I do recognize it.

Q. Was this in fact the document used in this briefing?

A. I don't recall whether this document per se was used or whether he used flip charts that reflected these words or something. But it was a background document that the staff would have used to prepare for the briefing. Whether it was used or not, I don't know.

Q. Let me note for the record that the cover of this paper identifies the authors as Larry Kobren and Fernando Villarroel, both of who are subordinate to you; is that correct?

A. Neither report to me——

Q. They're subordinate to you?

A. Yes.

Q. In your opinion did this briefing paper contain all the pertinent information regarding the safety of reuse?

Mr. SCARLETT. I would request that Mr. Benson be allowed time to review the document to give a meaningful response to that answer.

Mr. MICHIE. Please, take your time. And while you're doing that, why don't we take a 5-minute recess.

The WITNESS. Fine. That includes me.

[Short recess.]

Mr. MICHIE. Back on the record.

By Mr. MICHIE.

Q. Have you had sufficient time, Mr. Benson, to review the briefing paper?

A. I read through the briefing paper. The simple answer is——

Q. Let me repeat the question so that we're sure that we're all on track here.

A. OK.

Q. In your opinion did this briefing paper contain all of the pertinent information regarding the safety of reuse that should have been given to the Commissioner?

A. The purpose of the briefing was to get him—you know, to give him an overview of the dialysis/reuse issues. Clearly we couldn't give all the pertinent information. The intent of the briefing was to, in a limited amount of time, give him the best information we could to get him up to speed on whatever he might have needed to know.

Q. If you would, please turn to page 4 of the briefing paper, the title of which is "Reuse Safety,"

A. Right.

Q. At the top of the page it states, quote: "Studies have shown that reuse is as safe as nonreuse if"—the word "if" underlined—"dialyzer reprocessing is done adequately. Reuse patients"—and I'm inserting the word "are" unless you have some disagreement with that—"reuse patients are shown not"—word "not" underscored—"to be at a disadvantage compared to other patients."

This briefing paper was passed on to Dr. Marshall for his preparation of the testimony. Would it have been informative to both the Commissioner and Dr. Marshall if this briefing paper had pointed out that reporting to the FDA of injuries, accidents, malfunctions, and poor quality control associated with reuse in dialysis clinics is not mandatory and that therefore no one, including the FDA, can be certain of the safety of patients in these clinics?

A. I think that that's true. But neither is it required to report first-use syndrome effects. And studies again have shown that there are—and if you look through the anecdotal information in that Dierksheide package, you'll find some first-use problems also there. So I think that in my mind at least the two balance each other out.

Q. Do you find—I'm sorry, go ahead.

A. Well, no, I'm just saying that I think, like I said—this package—this was used to speak from for both Villarroel as well as Kobren. And I don't recall what they said, but you can't possibly cover all the bases. So I feel OK about the document.

Q. If I can repeat the question again, do you think it would have been informative to both the Commissioner and Dr. Marshall if this briefing paper had reflected in any way the fact that reporting of these injury malfunctions, poor quality control, et cetera, was now mandatory? Would that not have been informative?

A. It would have been as informative as telling them that the reporting of first-use syndrome problems were not mandatory.

Q. Do you find any reflection in the paper regarding first-use syndrome?

A. I'd have to relook at it.

Q. As not being reported?

A. No, no; as not being reported, no.

Q. So neither piece of information was included in this briefing paper?

A. Right; it may have been included in the briefing. I don't remember.

Q. Well, do you think it's possible that the Commissioner would have been told that mandatory reporting was not in place?

A. Mandatory reporting was in fact in place at the time of this briefing.

Q. Not for dialysis clinics?

A. Well, for dialysis equipment.

Q. But not for dialysis clinics?

A. No; not for dialysis clinics.

Q. And that's the very point that I was asking you about.

A. True.

Q. Dialysis clinics, am I correct, are not covered by GMP's or by MDR, mandatory medical device reporting?

A. Correct.

Q. Which, of course, is your mandatory reporting system?

A. That's correct.

Q. And the clinics are not covered by MDR; is that correct?

A. That's correct.

Q. Let me note for the record that a statement regarding a lack of mandatory reporting by dialysis clinics can be found on page 9 of the FDA's May 16, 1986, reuse options paper. Also a similar statement appears on page 19 of the FDA reuse committee's July 28, 1986, version of its report, "Options for the Managing of Medical Devices."

By the way, did you—were you able to brief—give Dr. Marshall a briefing on this paper prior to his testimony?

Mr. SCARLETT. Could I ask the record reflect which paper?

Mr. MICHIE. The briefing paper that's before the witness, that was prepared initially for the Commissioner.

The WITNESS. Oh, I thought you were talking about the other one, the one you just mentioned. I don't know whether anyone else did or not.

By Mr. MICHIE.

Q. Would it also have been informative to Dr. Marshall and to the Commissioner as well if this paper had stated that without oversight FDA cannot be confident that reprocessors are conforming with reasonable protocols and that reprocessed devices are as safe and effective as the original?

A. Those are tough questions to answer because—I mean, of course it's infomative. I mean there are 10,000 things that you could say that would be informative. So the answer is "Yes," it would be informative. But lots of things would. I don't——

Q. But this would have been informative if that had been included in the briefing paper? Is that correct, is that your feeling?

A. Yes; sure.

Q. For the record, this statement that I've just read regarding the absence of oversite by FDA can be found on page 11 of the FDA Reuse Committee's May 16, 1986, reuse option paper.

On page 4 of that same briefing paper that initially was put together for the Commissioner is a reference to several papers published in 1980, 1981, and 1982, if you would refer to page 4 of the briefing paper, the briefing paper that went to the Commissioner.

A. Yes; but I wish to insert something.

Q. Oh, please.

A. This document that you're referring to, there was no intent to report to the Commissioner the Reuse Committee's findings or on their recommendations. You're implying that——

Q. No, no; let me correct you. I'm not implying anything of that kind.

A. Fine; it sounded like that to me.

Q. We're talking about the briefing paper on page 4 with reference to several pages. Am I correct in assuming that the purpose of these references was to support the conclusion in the briefing paper that, quote, "reuse patients are not"—"are shown not to be at a disadvantage"? Was that the purpose of those references that appeared directly below that statement?

A. Yeah; let me answer you this way: at this time the Senator's concerns about reuse were well known. And I think there was an attempt to lay out before the Commissioner reasons that—well, to put that into context. So I think if the focus of this document seems to be that—to focus on the advantages or the safety side of reuse, it was for that reason.

I don't remember what set the briefing up. He may have asked for a briefing focusing on reuse. And I don't remember that.

Q. Again, if I may ask you, I'll repeat the question, were these references used to support the conclusion in the briefing paper that reuse patients are shown not to be at a disadvantage? Were they not used to support that statement?

A. Let me reread this. Yes.

Q. Among these references is a publication, quote, "Multiple Use of Hemodialyzers-Deane Report, 1981." Have you or to your knowledge have the authors of the briefing paper for the Commissioner ever at any time prior to or following the March 6 hearing read the so-called Deane report in its entirety?

A. I have not. I would hope that Kobren and Villarroel both have.

Q. Do you know this to be a fact?

A. I do not.

Q. Are you aware that this report was produced by the National Nephrology Foundation under contract to the NIH? And we will at this time provide you with a copy of the 1981 report. Do we have it here?

Mr. SCHULKE. It's not here. I can go get it.

Mr. MICHIE. Please do.

[Discussion off the record.]

Mr. MICHIE. Let the record show that the witness now has the document, the title of which is "Multiple Use of Hemodialyzers."

By Mr. MICHIE.

Q. Do you recall ever seeing that document?

A. I don't recall seeing it. I'm aware of its existence.

Q. Are you aware that much, if not most, of the information or data upon which Dr. Deane allegedly relied to write the report originated from the research and study by the subcontractor of the National Nephrology Foundation; namely, Arthur D. Little, Inc.? Are you aware of that?

Mr. SCARLETT. I'm going to object to the question. Mr. Benson has already indicated he's not familiar with this report. And I don't see any need to ask him a lot of detailed questions about it.

Mr. MICHIE. I don't understand the basis for your objection.

Mr. SCARLETT. You're asking the witness a question that he's already indicated that he is not in a position to answer.

Mr. MICHIE. I don't think that's entirely correct, Mr. Scarlett. What he stated was he doesn't recall seeing the report. That doesn't necessarily mean that someone within his charge or at the Center could not have briefed him on the contents or on the materials that I'm about to ask him. So I think the question is appropriate within those bounds.

Mr. SCARLETT. All right. You can answer the question by Mr. Michie.

Q. Repeating the question, are you aware that much, if not most, of the information and data upon which Dr. Deane allegedly relied to write the report originated from research and studies performed by a subcontractor of the National Nephrology Foundation, namely Arthur D. Little, Inc.?

A. No.

Q. Have you or to your knowledge has anyone else within your Center read the Arthur D. Little—ADL, as I will refer to it from now on—report entitled, quote, "The In Vitro Evaluation of Certain Issues Related to the Multiple Use of Hemodialyzers," and dated February 1981?

A. I'm not aware of that.

Q. Let me share with you now a letter dated October 9, 1981, to Norman Dwane, M.D., principal author of "Multiple Use of Hemodialyzers" from John Ketteringham Ph.D., vice president of ADL. Have you ever seen or been apprised of this letter prior to your appearance here today? And take your time to look at it.

A. Do you want to repeat the question, please.

Q. Do you recall having seen this letter prior to your appearance here, or having been apprised of this letter by anyone prior to your appearance here today?

A. I've never seen the letter before. I recall only that there was some controversy over the Deane report. Presumably this is the foundation for that, but I was not aware of what that foundation was prior to today.

Q. From whom did you receive this information about the controversy, as you put it?

A. I don't recall.

Q. Was this a long time ago or was it recent?

A. I would say—I really don't remember. Fairly recently, not ages ago.

Q. Within months or a couple of years?

A. Probably within months.

Q. Would you say it was prior to the March 6 hearing?

A. No.

Q. Following the March 6 hearing?

A. Probably.

Q. Does that jog your memory at all on who might have informed you of this controversy?

A. I mean I could speculate as to who would have said it. But, no, I don't recall.

Q. For the record I will read excerpts from the ADL letter. "The final report of multiple use of hemodialyzers was submitted to NIH without benefit of review at ADL. Clearly the interpretations and conclusions presented in the final report to NIH are those of the National Nephrology Foundation and not of ADL. We urge that conclusions such as those relating to the concentration of formaldehyde used for sterilization be substantiated where appropriate by clinical trials as was envisaged in the original request for proposal of this assignment.

"The final report omits most of the limitations which attended data and statistical statements in the ADL report for those ADL generated data and statements which were selected. In particular the final report tacitly asserts that the dialyzers which NNF, National Nephrology Foundation, submitted to ADL for testing were sufficient in number and representation to permit conclusive statistical comparison.

"The ADL report makes no such assertion and in fact advises that more extensive testing be performed to substantiate its qualified findings. There are a number of tables presenting data or statistical conclusions in the NNF report which are attributed to the ADL report, when in fact the tables either in total or in part are not derived from the ADL report," the word "not" underscored by the author.

"Since our report is a major reference, we hope that it, this letter, and the attached comments will be made readily available to those receiving copies of the final report."

Are you aware that Dr. Deane the NNF, and NIH failed to address the complaints and charges of ADL contained in this October 9, 1981 letter?

A. No.

Q. Are you aware that NCHSR staff met with Dr. Deane following the March 6 hearing to discuss the controversy raised by the ADL letter and that Dr. Deane was unable to refute the complaints and charges in ADL's October 9, 1981 letter?

A. No.

Q. In light of what we have just shared with you regarding the Deane report, was the Commissioner or Dr. Marshall given all of the pertinent facts concerning this report and the briefing paper to the Commissioner that was passed on the Dr. Marshall, this report as you stated earlier supporting the statement that reuse patient were not at a disadvantage?

Mr. SCARLETT. I object to the question. You're asking the witness to reach a conclusion that he couldn't possibly reach based on about 5 minutes exposure to this letter. You are asking him to characterize it, evaluate its relevance, characterize the significance of the letter in relation to information that was provided, and then reach a conclusion. You've only given it to him 5 minutes ago. He can't give you a meaningful answer to that.

Mr. MICHIE. So you're objecting on the grounds that he hasn't had a chance to read the letter; is that correct?

Mr. SCARLETT. He has not had a chance to read and evaluate the letter, that is correct.

By Mr. MICHIE.

Q. Are you refusing to answer the question on advice of counsel?

A. Repeat the question.

Q. The question again, in light of what we've just shared with you regarding the Deane report, the October 9, 1981 letter that you have before you, was the Commissioner or Dr. Marshall given all of the pertinent facts concerning this report in the briefing paper?

A. I was going to say that you're asking me to make a conclusion, I really was, that I can't make. I don't know the answer. I don't know to answer that. It's not that I refuse to answer, I don't know how to answer.

Q. In light of the fact that this is the first time that you've seen this letter, then as principal briefer at this briefing of the Commissioner, you could not have told him about the letter or about the controversy; could you have?

A. I was not the principal briefer. But the answer is no, I couldn't have.

Q. Did anyone at that briefing inform the Commissioner of the controversy and of the charges and exception taken by ADL with regard to the report?

A. I don't recall.

Q. If at that time you would have known of this controversy, do you think this would have been a pertinent piece of information in order to qualify this report in its support of the statement that reuse patients are not at a disadvantage?

A. What I don't know is the extent to which the Arthur D. Little concerns are scientifically valid. And I wouldn't—if I were—if one were to give me the assignment to find out how pertinent their concerns are, I would ask someone with scientific knowledge, with good statistical knowledge, to look at the issue. I wouldn't trust myself to make that conclusion.

So I don't—I mean I don't know. Scientists often bicker back and forth extensively over issues such as statistical validity of a given sample. I would have to look very carefully at that. I think—I would think that had we been aware that there was controversy, then it would have been a responsible thing to do. We may have. I just don't recall.

Q. In light of your having seen this letter today, do you think this issue should be pursued?

A. Well, I don't think that our knowledge of the degree of safety associated with reuse would be proved or unproved by one single report.

Q. Granted. But you did use that report in order to buttress the statement that reuse patients are not at a disadvantage?

A. Buttress is a vivid word. I think——

Q. Let's use the word support.

A. It was showing literature that dealt with the reuse issue. I think that if we could have had knowledge of literature that made the opposite point, we would have also referenced that.

Q. Did you reference any reports or papers on that page 4 regarding the safety of reuse that were, as you put it just now, to the opposite?

A. I don't know—I didn't do—I didn't write the paper, so I didn't do any of it. But I don't know——

Q. Well, let's turn now to another report also referenced on page 4 of this briefing paper entitled "Investigation of Risks and Hazards Associated with Hemodialyzers-FDA Report, 1980." We have a copy here for your reference of the report in its entirety along with a separate copy of chapters 1 and 12. Chapter 1 being the introduction and chapter 12 pertaining to the reuse issues.

Mr. SCARLETT. Do you want to take time to read that?

The WITNESS. I do not. It would be silly.

By Mr. MICHIE.

Q. Now, if I may assist you in the very first paragraph of chapter 1——

A. Is that this?

Q. Just turn the page there, and I think you'll find chaper 1.

A. Yes.

Q. In the very first paragraph of page 1, quote: "The study's aims were to identify the risks and hazards associated with hemodialysis equipment and to recommend ways of controlling it. The FDA has two goals in mind, to provide the division of general medical device standards with the information required for writing and implementing standards for hemodialysis equipment and to provide the gastroenterlogical urological device classification panel with additional data to aid its evaulation of system component devices."

Now, had you been aware of the purpose and goals of this study prior to your appearance here today?

A. Well, I was aware of this document. If you had asked me what the goals were, I think I would have had to have looked them up.

Q. Let's turn now to chapter 12 of your report. If you would go on in a few pages, I think you'll find chapter 12, the first page. It's titled "Reuse of Dialyzers."

A. Uh-huh.

Q. Have you ever had the occasion to read this chapter of the report?

A. I don't think so.

Q. Let me direct you to the third paragraph on page 338, which states, quote: "The safety and efficacy of reuse is a subject of some controversy. While there are some reports in the literature that document the adverse effects of reuse, there are others that indicate that dialyzer reuse is a safe and effective practice with minimal patient complications. The studies cited in the literature are not always complete, well controlled, and well documented and an objective interpretation of the results is difficult."

Skipping now to the middle of page 343, we find the statement "HIMA," standing for the Health Industry Manufacturing Association, "appropriately points out that the practice of reuse is largely unregulated and therefore does constitute a potential threat to patient's safety."

Now, can you point to anything contained in the passages I've just read that reflect in any way the statement in the briefing paper for the Commission, quote, "reuse patients are shown not to be at a disadvantage compared to other patients"?

A. I don't feel like going through that kind of exercise this afternoon, Jim. It's just not appropriate to this session. If you want to make the point that you believe that this report doesn't support that reuse is safe, then make it. I'm not going to sit here and try to go through that kind of exercise. This is a thick report, I'd want to look at the whole report, so on.

Q. We would be happy, Mr. Benson, to allow you to postpone your answer to these questions to a later date, that, of course, with the agreement of your legal counsel. We are not trying to get you to answer questions about a report that's 2½ to 3 inches thick. But we do want to get these questions on the record. And if you wish, we can defer your answers until a later date if you wish to review the report.

Would that be agreeable?

A. Well, I would prefer to not answer questions of that nature. I don't feel like I'm expert enough for one thing. It's late in the day and I don't feel—I don't—I just don't think it's appropriate.

I—from my standpoint, I don't know what the ground rules on this sort of thing call for.

Q. Well, if you——

A. I have no objection to answering in writing those kinds of questions. But I'd want to have them adequately staffed out, and I'd like to do it right.

Q. I'll be glad to explain to you the rules. If you are at this time refusing to answer the question——

Mr. SCARLETT. Oh, Jim, let's go off the record.

Mr. MICHIE. Let me finish the sentence please, Mr. Scarlett.

And at the same time if you are refusing the accommodation that we have offered you, to take the report and review it from cover to cover if you wish and then answer your questions in writing or orally, whichever, but of course subject to the oath that you've taken this afternoon, I'd like your answer.

Mr. SCARLETT. I'd like an opportunity to consult with my client.

Mr. MICHIE. Fine. You have those two options.

The WITNESS. Oh, I have lots of options.

Mr. MICHIE. Let the record show that the deponent along with his legal counsel have left the room to consult privately regarding the last question on the record.

[Short recess.]

Mr. MICHIE. Are we back on the record?

Mr. SCARLETT. We're back on the record.

I believe Mr. Benson would prefer to go ahead and answer the question based on the knowledge that he has at this time.

The WITNESS. Would you mind repeating the question.

By Mr. MICHIE:

Q. Yes. Going back, we'll start from the very beginning, the third paragraph, page 338, which states:

> The safety and efficacy of reuse is the subject of some controversy. While there are some reports in the literature that document the adverse effects of reuse, there are others that indicate that dialyzer reuse is a safe and effective practice with minimal patient complications. The studies cited in the literature are not always complete, well controlled, and well documented and an objective interpretation of the results is difficult.

Then we skipped on over to the middle of page 343 where it states: "HIMA," standing for the Health Industry Manufacturers Association, "HIMA appropriately points out that the practice of reuse is largely unregulated and therefore does constitute a potential threat to patient safety."

My question was: Can you point to anything contained in the passages, excerpts that I've just read that reflects in any way the statement of the briefing paper for the Commissioner, "reuse patients are shown not to be at a disadvantage compared with other patients"?

A. OK. Give me a second.

Q. Sure.

A. There's one passage on page 338 that you read, I would like to repeat a portion of that.

Q. Please?

A. It says: "There are others," referring to studies, "in the literature that indicate the dialyzer reuse is a safe and effective practice with minimum patient complications." That to me presents a balanced view of the reuse versus nonreuse issue.

Q. Do you find that same qualification that you've just cited in the statement that reuse patients are shown not to be at a disadvantage?

A. I'm sorry, say it again.

Q. I'm trying to understand—you know, I read that passage and it says some studies say there are problems, some studies say there aren't.

A. Right.

Q. I'm trying to get you to tell me whether or not you see that reflected in the statement from the briefing paper, "reuse patients are shown not to be at a disadvantage." It doesn't say reuse patients most of the time are shown not to be or some of the time. But it implies that reuse patients are shown not to be at a disadvantage all the time.

A. The passages that you read don't indicate that reuse patients are not at a disadvantage all the time if that's what you're wanting me to focus on.

Q. Then the passages that you read and that I read from the paper, do they accurately reflect the statement reuse patients are shown not to be at a disadvantage? Not some reuse patients, not most, not a few, not all, does it reflect that?

A. Yes; I think it does.

Q. On the last page of chapter 12, page 344, there's a paragraph with a heading "Recommendations," which states:

> The issue to be resolved is whether standards, either performance or disclosure, can be written for the reuse of dialyzers. At the present time such standards cannot be proposed for two reasons. First, in the absence of definitive studies, such as the one contemplated by the NIH, the necessary criteria to establish standards cannot be formulated. Second, at the present time manufacturers label dialyzers as being intended for single use only. Unless these issues are resolved standards related to reuse are not relevant.

Now, can you point to me anything in these conclusions and recommendations at the end of that chapter on reuse that reflects in any way the statement in the briefing paper for the Commissioner, that "reuse patients are shown not to be at a disadvantage," the word "not" underscored, "compared to other patients"? Can you show me any thing there?

A. No. I don't think it's—to me this recommendation, this paragraph, doesn't zero in on reuse at all. It's simply a statement of dialysis equipment in general.

Q. Well now, what is the title of chapter 12, Mr. Benson?

A. I don't know. What page does it start on?

Q. Chapter 12, the title of chapter 12 is "Reuse of Dialyzers."

A. What page is that?

Q. That's on——

A. Here it is, 338.

Q. Now, what my question to you is that—can you explain why this 1980 FDA report—and if you wish you can postpone your answer to this question—why was this FDA report used to support the statement to the Commissioner and to Dr. Marshall, because the paper was passed on to him, that reuse patients are shown not to be at a disadvantage?

A. I can't answer that now. From the passages that you've pulled out with the exception of the one example that I gave, it certainly doesn't make the case, including the example I gave, I certainly don't believe that it makes a strong argument——

Q. May I make a suggestion?

A. May I finish?

Q. Go ahead, Please.

A. I can't answer your question without having either myself or someone go through the report and dig out that information.

Q. Agreed. And my suggestion is that if you will go back to your office, get a copy of this report, go over it, and see whether or not anywhere in that voluminous report you can find a statement or a combination of statements that support what was told to the Commissioner in that briefing paper, quote, reuse patients are shown not to be at a disadvantage compared to other patients? Would you like to do that, Mr. Benson?

A. Is that in the form of a suggestion?

Q. It is a suggestion.

A. OK. I will weigh that suggestion.

Mr. Scarlett. I'd like to state for the record in the form of an objection if necessary that your characterization of the briefing paper as reflecting what was told, the Commissioner is inaccurate. The briefing reflects what's in the briefing paper. It is not a transcript. I don't think Mr. Benson stated that everything that's in the briefing paper was conveyed to the Commissioner nor did he state that they were only things that were conveyed to the Commissioner.

By Mr. Michie.

Q. Was the Commissioner apprised of the passages in this report and was the Commissioner apprised that this report was focusing on whether or not standards could or should be formulated and put into place, was he told that at the briefing?

A. I don't remember what he was told at the briefing. I can tell you that we believe—we in the Center beleive, I'm sure we believed at the time of the briefing, we beleive now, that it would be a positive act to have protocols in place in dialysis centers, both for all facts of dialysis as well as reuse. So it would not have been unlikely that we would have said that.

Now, standards is a term that's often misused and it needs to be defined. In the context of this report as I was reading it, I read it was equipment performance standards. I think that your context and that context that I'm using it in now, is as a protocal, which would describe how one goes about the technique of hooking up dialysis equipment, proper cleansing and so on.

Q. But you're not certain of that; are you?

A. Of what?

Q. The conclusion you just reached, that it's performance standards?

A. Oh, no, not at all. I don't know.

Q. In other words, you wouldn't be able to make a definitive statement on that unless you read the entire report; would you?

A. That's right.

Q. Let's move forward in time now to July 8, 1986. Did you attend a meeting on that date with Dr. Windom, Assistant Secretary for Health, and a number of other PHS personnel?

A. I did attend the meeting. And that's probably the right date, I don't know.

Q. What was the purpose of that meeting?

A. The purpose was—I think were two purposes. One was to—Dr. Marshall, a far as I know instigated the meeting and had two purposes. One was to brief or to try to get Dr. Windom up to speed on the dialysis issue, if you will. He was newly appointed as Assistant Secretary for Health. He also wanted to seek a delay in the deadline that he was under for the assessment report.

Q. The deadline you say?

A. Yes; that's what I said.

Q. And who at the meeting discussed a deadline; do you recall?

A. No. I'm—my recollection is if that was the purpose of the meeting, presumably Dr. Marshall did. I can't give you verbatim, but I'm pretty sure he did discusss that.

Q. Do you recall the date of this deadline as you put it?

A. No; but—in fact, I thought that the report had been due alrady. So I'm not sure.

Q. Roughly for how long a time did this meeting last? An hour, less than an hour?

A. I would say—on the order of an hour.

Q. Were you there for the entire meeting?

A. Yes.

Q. Was Dr. Windom there for the entire meeting?

A. He may have been called out for a phone call or something. But for the most part he was.

Q. As best you can recall, you talked about the deadline, you talked about briefing, but very, very briefly in summary would you tell us what direction did this discussion take and who did most of the talking?

A. Do you mind holding just a second? I want to make a note.

Q. Sure, take your time.

A. I'm back on the other thing.

Q. That's all right.

A. OK, I'm sorry.

Q. That's all right.

A. Would you again.

Q. If you would give us some flavor in a summary way about this discussion. You spoke of the deadline, getting Windom up to speed, is that correct, on dialysis, and who did most of the talking, if you could just give us a general overview of what was said there as you recall.

A. Dr. Windom was very passive at the meeting and was kind of, you know, in a receiving information mode. It was the first time I had met him so I was—I didn't know what to expect. So that's how I would characterize it.

Dr. Marshall actually came to the meeting at 4:30, give or take a few minutes. Prior to that time the rest of us there sort of stumbled around not knowing exactly what to do. It was a little bit awkard in that it was Dr. Marshall's meeting and it was a what do we do now kind of thing. And we ended up giving him a rather brief overriew of the hearing and the issues that led up to the hearing.

Q. The March 6 hearing?

A. The March 6 hearing. Bob Eccleston did that—well, period, he did. When Marshall came in, he then talked about concerns that he had about the process——

Q. About which process?

A. The process leading up to the input to the assessment report, the fact that he had gotten materials very late in the game and needed additional time, those kinds of issues. There probably were lots of other things. I'm not sure I remember them all.

Q. Did Dr. Marshall complain about not getting materials in a timely manner from your Center, your agency?

A. I know that's an issue. And I don't recall——

Q. At that meeting?

A. Yes, I know. I don't recall him putting that on the table at the meeting. He may have. If he did it, he did it in a very gentle way that I didn't feel—I mean I would have been tuned into that because it was the first time I had met Dr. Windom, it would have been very uncomfortable to be so accused. I didn't feel accused.

Q. Do you recall having received during this meeting a copy of a memo addressed to Dr. Windom from Dr. Marshall?

A. I recall that a memo was handed out at the meeting.

Q. Do you recall receiving a copy yourself?

A. I was given a copy, yes.

Q. And did you read it?

A. I did not.

Q. You did not read it?

A. I did not.

Q. Why didn't you read it?

A. Well, the discussion went on—like I say, he came in late, the memo was handed out. And it was never discussed per se at the meeting, I mean the content of the memo was never discussed.

Q. And you have never read that memo to this day?

A. Oh, I read it.

Q. Is that correct?

A. No, that's not correct.

Q. Oh. When did you come to read this memo?

A. As a result of your sending it to the Secretary, Senator Heinz sent it to the Secretary.

Q. So this was some time shortly after July 23?

A. Yeah, right.

Q. At this time we'd like to share with you a copy of that July 8 memo. This memo in part states: "As events have unfolded it is clear that the March 6 testimony was not based on all of the germane facts and that we may need to take a position counter to that which we argued on March 6."

Mr. SCARLETT. Could you state where in the memo you are?

Mr. MICHIE. That's on the first page, right up in the first paragraph. The sentence starts: "As events unfolded."

Mr. SCARLETT. OK.

By Mr. MICHIE.

A. It goes on to say: "We need to ascertain a PHS position and inform HCFA of that position in order to minimize embarrassment for the Department."

Q. Do you know what Dr. Marshall was referring to regarding events that had unfolded? Do you know what he was referring to?

A. Let me think about this. Well, the clear answer is no, I don't know what he meant. I know that—I know some of the concerns that he had were, from later discussions were he didn't feel like he had all the data that was available, that was certainly a concern. That's my interpretation.

Q. Was he accurate in stating so to you?

A. As far as I know he was, yes.

Q. So are you sayng that he could possibly have been referring to the FDA and the other agencies not having provided him with all of the information and documentation that at the time of the March 6 hearing was in the possession of the FDA and perhaps some of these other agencies? Do you think that's what he might have been referring to?

A. I would guess that's what he meant, I think that's what he meant.

Q. Do you have any knowledge of, as he put it, germane facts missing from his testimony?

A. No, I do not.

Q. Do you have any knowledge of the germane facts that he might have been referring to regarding Mr. Villforth's extemporaneous testimony at the hearing?

A. No.

Q. Have you discussed this with Mr. Villforth at any time following the hearing?

A. Yes.

Q. What did you discuss with him?

A. Just the general issue of what was missing, you know, what was the issue, what was the concern. I don't—the—my attitude has always—was and has been that FDA never withheld information or certainly didn't intentionally withhold information.

Q. Do you know that for certain?

A. I know it from my own attitude in——

Q. But I mean can you speak for the other parties who are involved?

A. No; I can't speak for anyone else's incentives or motivations. But I know those people well and I don't think—I think that there is a difference between a response of going in and, you know, emptying your files and, you know, versus trying to be cooperative.

We had set up at Dr.—I'm not sure at whose request. Someone from Marshall's staff had contacted our own health affairs staff at the FDA level. They in turn requested us to assist Marshall. And I think I in fact answered that request. And we said we'd do whatever we could. And that was always my attitude.

I thought, and still do think as a matter of fact, it was a relatively close working relationship with Dr. Marshall and with Dr. Carter and anybody else over there that was working on the assessment. We were willing to do whatever we needed to do to help them. I don't think we withheld information.

Q. Turning now to page 3 of the July memo, the first two sentences in the second to last paragraph, quote, "After the hearing Dr. Macdonald directed me to carry out an assessment of dialyzer reuse"——

A. Just a second.

Q. Page 3?

A. OK, where are you?

Q. First two sentences of the second to last paragraph.

A. OK.

Q. "After the hearing Dr. Macdonald directed me to carry out an assessment of dialyzer reuse. In the course of carrying out that assessment it has become evident that communication within the Public Health Service is less than adequate."

What during the course of carrying out of this assessment do you think would have made it evident to Dr. Marshall that communications within the Public Health Service were less than adequate; do you have any idea of what he meant?

A. I really don't.

Q. Have you ever discussed that with him? Have you ever asked him what he meant by that?

A. I've never asked him directly.

Q. Have you discussed this July 8 memo with him in any context whatsoever?

A. There was a session when he came over and met with us when the rumor of the hearing was going around. And he had actually done some thinking about what ought to be said at that hearing. And I don't remember talking about the memo as such at that session, but I know we talked about his concerns about information.

And it was sort of—from my standpoint it was kind of an air cleaning session because I wanted to say to him, look, we are not and don't want to be withholding information. The one thing that he expressed concern to us about was the two draft reports, State reports, that in fact were in our possession prior to the hearing. And I can remember—the reason I mention that in particular is I remember saying to him, John, if they were withheld—John Marshall, if they were withheld from you they were also withheld from John Villforth.

Because John—John Villforth didn't have them either. And I went back and looked at that specifically because it did concern me. And the answer that I got back, and I beleive it, was simply the report—one of the reports was in pretty bad shape and the project director didn't have a chance to look at those, and didn't make the connection between the potential importance of those reports and the hearings. I believe him.

So that was the nature of the discussion to answer your question.

Q. Isn't it true though, Mr. Benson, that most of this material—and I speak of the substantial amount of documentation, much of which this committee was provided by your Center, isn't it true that most of this material was not provided to the NCHSR until after that agency had completed its assessment and had submitted its report to Dr. Windom on August 6; isn't that the case?

A. I know there was a substantial amount of material that you delivered to Marshall that he had not gotten from us that came from our files. Whether you call that substantial or not, I don't know, I didn't do a page count. But I think that it's important to know that. As far as I know anyway we were never under a request to dump the files.

It was a cooperative arrangement, including having people to sit down and work with him on the assessment report. We had people over there, we had people answering questions, working with him very closely. So I think there was a difference between your requests, which I can't give to you verbatim, but basically your's are give us all the information that you have in your possession, versus his which would be to standby to help. And it was the standby to help thrust that we had with Dr. Marshall, et al.

Q. Now, what we're talking about are the documents, the medical device reports, the establishment inspection reports, the many memos and other records that were written beginning in early April and even before that regarding infection outbreaks in dialysis clinics that reuse, as well as the EIR and NDR reports pertaining to deaths, serious injuries, malfunction, extremely poor reprocessing procedures in dialysis clinics, and numerous deficiencies in manufacturing in terms of manufacturing dialysis and reprocessing devices.

Shouldn't this material have been provided to NCHSR in a timely manner? Much of this had been generated even prior to the March 6 hearing?

A. I can't give you a simple yes or no answer to that. I think that—I made an attempt to inform Dr. Marshall of the, either directly or by memo through Eccleston or someone—on some of the infection outbreaks which were late in the game. I know that if you asked about EIR reports, I mean there are literally thousands of EIR reports floating around, and I wouldn't——

Q. But not just on reuse and reprocessing and manufacturers. There aren't that many of those, are there?

A. Probably not. But I'm giving you as good an answer as I can.

Q. Alright.

A. It would probably not have occurred to me to deliver those to him.

Q. Are you aware that on or about August 8 of this year Robert Eccleston of your staff finally telephoned the NCHSR staff to inform them that your Center would begin to provide to NCHSR everything that your Center had already provided or was in the process of providing to this committee? Are you aware of that,

A. I'm not sure of the date or the actual content. But I—yes, I'm aware of that.

Q. I have here for your reference a copy of a memo dated April 9, 1986, to the FDA's Associate Commissioner for Health Care from NCHSR's Office of Technology Assessment in which NCHSR requested any and all information regarding dialysis reuse from FDA. There is a schedule there regarding these issues.

Have you ever seen this memo prior to your appearance here today?

A. No.

Q. Would you like to take a minute to look at that here today.

A. Yes, I would.

Q. Incidentally, this memorandum—duplicates of this memorandum were sent to CDC and I think to one or two other interested agencies.

A. No. My recollection is that we got a memo much briefer than this from the health affairs staff making a request for assistance. But it was not this extensive, that request was not this extensive.

Q. You have a definite recollection there of never having seen that memo until your appearance here today; is that correct?

A. Well, let me tell you exactly what's running through my mind. I—in reviewing things yesterday—and again I told you I tried to review things I had been associated with—one of the things was a response to the Office of Health Affairs. And the——

Q. Whose response?

A. My response. And the incoming that accompanied that was a briefer memo than this. So based on that, looking at those two documents yesterday, I don't recall this longer version.

Q. Now, let me share with you now a May 28, 1986, memo to NCHR's Office of Technology Assessment from FDA's Office of Health Affairs. This memo is in response to the NCHSR April 9 request that you have before you there for information. This memo states:

> All information concerning the issue of reuse of dialyzers, blood lines, trans-use filters and dialyzer caps is already available to OHTA as part of the package prepared for the Senator Heinz March 6, 1986 hearing. Office of Device Evaluation has no additional information.

Again pointing out this memo is dated May 28 of this year.

Now, was this a true statement at that time, Mr. Benson?

A. Probably not.

Q. Well, was it or was it not?

A. Well, it was obvious that additional information—I mean it's obvious that additional information was provided. So they didn't have all the information.

Q. As a matter of fact, as early as early April, weeks prior to the forwarding of the memo to NCHSR, FDA as well as CDC was very well aware of the fact, were they not, that outbreaks of infection were occurring in several States. Isn't that the case?

A. I don't know—we were aware that there had been outbreaks. I don't remember the dates. But I—I mean I trust your—I'm sure you have them down.

Q. Well, if you like, you can check your records and you can amend your answer to this question.

A. No, I don't need to do that.

Q. You're provided that accommodation.

When did you and your Center first learn of the infection outbreaks in several states that came to light starting in April, early April, of this year? Do you remember when you first learned about this? And how did you come to learn about it?

A. Let me answer you this way: I think there have been—if you go back over the DEN reports or various information, there probably have been—I know there have been infection or bacterial outbreaks of one kind or another associated with dialysis for a long period of time.

Again, I think that the hearings had everybody's sensitivity up, and so it was much more likely that our Office of Compliance, who normally is the link between myself or Villforth and the field. They manage the DEN program as well as the MDR program, so they would have had that information. So I don't recall specifically.

But my assumption is I would have found out from someone in the Office of Compliance about those outbreaks. And I think—again, I'd want to go back and look at the records, but it seems like it was around April that there was the—can I talk about trade names? Well, there was one that was recalled, and it was around that time.

Q. That was the chemical ReNew-D; isn't that correct?

A. Right.

Q. And the first outbreak of infection involving the chemical ReNew-D, was it not in Inglewood, CA? Do you recall that FDA personnel jointly with CDC personnel began an inspection at the Inglewood, CA, clinic on May 10?

A. I don't recall the dates. But I know we did—we had worked with CDC on a follow-up to several of those outbreaks.

Q. When was it that you and your Center began to inform NCHSR of these outbreaks? And to whom in NCHSR was this information given?

A. I don't know the answer to that.

Q. Was NCHSR informed of these infection outbreaks in writing? And if so, approximately when were these written communications forwarded to NCHSR?

A. I know that when—it was a period of time around this time when I became aware of the infection outbreaks. And I also realized that we ought to be letting Marshall's crew know what was going on. So I sent one note over there and asked Eckleston, who by this time we have asked to be kind of the focal point within the Center for dialysis related issues, to keep him informed.

So, I think you asked before what's triggered some of the increased information. That could have been what triggered it. I know that I was concerned that we wanted to make sure that we were providing as much information as there was.

Q. So as best you can recall, you do remember sending one note or a memo over to Dr. Marshall?

A. Yes; I do.

Q. Do you remember when that might have been? Was it in April. Was it in May? Was it in June; do you recall?

A. I don't remember the dates.

Q. We have a copy here of a June 25, 1986 memo to Dr. Marshall in which you apprise him of the ReNew-D recall and the infection outbreaks associated with the use of that chemical. Was this the note you were referring to?

A. Yes; I think so—yes, it is.

Q. Was this your first written notification to Dr. Marshall concerning this?

A. I believe it was.

Q. Now, going back in time, I think you stated earlier that you believe it was some time in April or maybe as late as May that you learned abut the beginning of these infection outbreaks.

A. Well, personally or as a Center?

Q. Well, as a Center?

A. As a Center, yes.

Q. Can you explain to me why it took so many weeks from the beginning of those outbreaks in early April for you to inform Dr. Marshall of what was going on? Can you explain that to me, that memo being dated June 25?

A. I think the answer is it didn't occur to me at the time to inform them. I mean it just wasn't in my mind to inform them.

Q. In view of the fact that Dr. Marshall was in the process of conducting a health technology assessment of the safety and efficacy of reuse, are you saying that you did not think that this was germane to his assessment?

A. Well, obviously I did when as soon as it occurred to me that this was something that Marshall should know, I followed up on it.

Q. Did anyone suggest to you or did you decide on your own not to inform NCHSR until June 25?

A. Absolutely not. No one has ever suggested to me that we not inform Dr. Marshall or anyone reporting to Dr. Marshall these sorts of things.

Q. In retrospect, do you think you should have informed him prior to June 25? In light of the fact that the documentation, virtually all the documentation, pertaining to what you talk about in that memo to him he did not receive until August 11, 5 days after his deadline of August 6 to submit the assessment report to Dr. Windom? In retrospect, do you think you should have reported to him sooner and shared all that material with him?

A. Oh, I understand the question. Let me think a minute. I think that as a Center we, in retrospect, as soon as the infectious outbreaks, occurred or as soon as we had knowledge of any dialysis issues, that we should have informed him, yes. But that is in retrospect. And I think that——

Q. Why did you think it didn't happen, Mr. Benson?

A. Well, I'm thinking of it—I'm personalizing it for myself. And I think that——

Q. But we're not suggesting that all of this responsibility was on your shoulders.

A. I know that.

Q. I'm trying to focus on the Center as an institution.

A. And I'm trying to answer you—I understand that. And I'm thinking of how I operate. And I think that as soon as it hit me, awareness that this was a problem, I let them know. And I think that should have happened with others.

I can't give you a better answer. Clearly, in retrospect, we should have kept him better informed.

Q. Let's return now for a minute to the July 8, 1986 meeting, involving Mr. Windom, you, and other individuals. During that meeting were copies of Dr. Marshall's July 8 memo made available to all present? I think you stated earlier that it was.

A. Well, they were handed out.

Q. Was there a discussion of this memo, specifics discussion of this memo?

A. I did not read the memo——

Q. No; but I mean in the meeting itself.

A. I'm answering your question.

Q. Alright.

A. I did not read the memo at the meeting. So any discussion of the subject matter of the memo I really wouldn't have known whether that was in the memo or not. So I don't recall whether or not that it was—whether it was discussed—whether the content of the memo was discussed or not. I'm not sure. I'm sure we talked about some of the issues that were there.

Q. Did anyone at any time during that meeting who was present admonish, reprimand, scold, or criticize Dr. Marshall in any way for having written his July 8 memo to Dr. Windom in the first place? Did anyone do that?

A. It was suggested at the meeting that the memo should be for discussion purposes and not forwarded to the Assistant Secretary. I'm not sure that fits the words that you went through, but that suggestion was made.

Q. To whom and by whom?

A. It was made—principally I guess it was made to Dr. Marshall.

Q. By whom?

A. As I recall, by Steve Grossman.

Q. And what is his position with the Department?

A. I think he's Assistant—Deputy Assistant Secretary for Health—Planning and Evaluation—I think.

Q. Did anyone at that meeting ask Dr. Marshall to retrieve all copies of that July 8 memo and dispose of it?

A. Well, at the time, not subsequently, but at the time I treated the subject kind of lightly. I mean I tossed my memo back in the pile, and that was the end of it as far as I was concerned.

Q. But did anyone ask Dr. Marshall to retrieve all copies of that memo and dispose of it?

A. I'm answering your question as best I can. That was my recollection of what happened. I don't remember those specific words.

Q. All right. Let's go over it again. What is your recollection? What happened?

A. At the end of the meeting or near the end of the meeting, it was suggested that the memo not be forwarded, not be sent as such to Dr. Windom.

Q. Wasn't he sitting right there at the table?

A. Yes; he was.

Q. How could it not be given to him when he was there and he had a copy before him?

A. I'm telling you what was said.

Q. But as I've just described it, wasn't that the case, didn't Dr. Windom have the memo before him?

A. Well, I don't remember whether he had the memo before him or not. I mean I had one before me and I never read it. So, it's kind of a moot point.

Q. Are you suggesting that everyone in the room accept Dr. Windom was given a copy of this memo?

A. No; I'm not suggesting that.

Q. Was he given a copy of this memo?

A. I presume he was, I don't know. I think like most of us he did not read it if he was. The discussion continued as I said earlier, Marshall came in late, handed the memo out. It was never really picked up and read.

Q. And once—as you stated a moment ago, once the decision was made not to forward this memo to Dr. Windom, then what happened?

A. It was a light—kind of a light thing. And I know I took mine and just—you know, Marshall was sitting a couple of people away—and I just sort of handed it up to him. I think everyone else—it seems that everyone else did the same thing.

Q. You don't recall anyone in that meeting instructing Dr. Marshall to dispose of all copies of that memo?

A. I don't.

Q. Do you have a definite recollection of that not having been said or words to that effect?

A. Well, as close as I can recall, the suggestion was made to not sent the memo. And that was the end of it.

Q. We have for your reference a memo dated April 21, 1986, to the Secretary from Anna Boyd, Policy Coordinator in the Department's Executive Secretariat, regarding Senator Heinz' March 21, 1986 letter to the Secretary, that letter on March 21, 1986 requesting that the Secretary impose the good manufacturing practices on reprocesses of these devices.

Had you seen this memo prior to your appearance here today?

A. I'd like to take the time to read it.

Q. Please do.

A. No; I don't—I've never seen this. I don't recall it.

Q. You don't recall seeing the April 21, 1986 memo to the Secretary from Anna Boyd; is that correct?

A. Right.

Q. Has anyone ever discussed this memo with you though? Without your having seen it in other words?

A. Yeah; I understand. The issue certainly has been discussed. But I don't recall ever discussing the memo, so I don't think so. The answer is no.

Q. Do you recall if anyone in your Center or elsewhere in the FDA could possibly have assisted in the drafting or review of this memo prior to it having been sent to the Secretary?

A. I don't know that anyone did that. I just don't know. I don't—doubt it. We usually don't talk to the folks downtown. I mean it's just—I don't think we did.

Let me call your attention to the fourth line from the top on the second page of this memo which reads as follows:

> FDA strongly opposes GMP standards in this area and has taken the position that we should tell Senator Heinz in this letter that the GMP regulations do not apply in order to close the door to further pressure from Senator Heinz—from the Senator.

What is the basis—can you tell us what is the basis for FDA's strong opposition to applying GMP standards from your perspective?

A. Yes; I think in my mind there is a legal issue as to whether or not GMP per se can be applied. That's one issue. That I would say is probably arguable, and resolution of that sort of thing is relatively straightforward. So, I wouldn't use strongly in that context. I don't think it's a good idea because of the things that I talked about earlier.

I would much favor—much more favor a different path to achieve the same purpose, which is to improve the practice that go on in dialysis centers. I think it would be more—other paths are more cost effective. That's my view.

Q. But now looking at FDA as an institution, obviously this person who works in the Executive Secretariat I believe of the Department had to get the impression from someone that FDA strongly opposes applying GMP standards. I'd like to ask you is it possible, is it probable, that whatever strong opposition exists in FDA, is attributable primarily to the lack of resources?

A. The lack of resources is a contributing factor in my mind—for not wanting to use GMP's in dialysis centers. I think we did some crude calculations and figured it would cost something on the order of $700,000 a year, assuming one inspection every 2 years. And that's a sizable hunk out of the budget, especially when the budget has been going down. So, yes; that's certainly a consideration.

Q. Would you say it's an important consideration?

A. Yes; I would, absolutely. But that consideration I think becomes even stronger when you recognize that the authority and the vehicle for doing those kinds of inspections exists under HCFA authority. And I think, you know, we've recommended that on a couple of occasions. So, I think that's a better pathway.

It's the cost and then there's almost a duplication of function. I don't know the frequency with which the HCFA state contract people actually go in and do those inspections. But they are doing them. And I think that if better—if protocols were in place, maybe that process were fine tuned, that that would be a superior method.

If you want to characterize my feelings as strong, I would have to include that part of it.

Q. Did you or to your knowledge did anyone else in your Center or elsewhere within FDA advise Ms. Boyd, the author of that memo, that FDA had taken the position that the Secretariat should tell Senator Heinz that the GMP regulations do not apply in order to close the door to further pressure from the Senator?

A. I don't know where that language came from.

Q. Do you know if FDA has succeeded in closing the door on Senator Heinz from their standpoint?

A. Obviously not.

Q. Well——

A. I don't take that lightly, I'm sorry.

Q. Is FDA still attempting to close the door on Senator Heinz?

Mr. SCARLETT. I'd ask that the question be clarified. I don't understand what closing the door means. This quotation is not something that's familiar to Mr. Benson, he has so stated.

Mr. MICHIE. If legal counsel would look at the material there, the quote from Ms. Boyd, she obviously is attributing this particular opinion to the FDA.

Mr. SCARLETT. But Mr. Benson has disclaimed personal knowledge. He is not the FDA. He's Mr. Benson.

Mr. MICHIE. Perhaps so. But all I'm asking is whether or not he has knowledge of FDA allegedly still attempting to close the door on Senator Heinz?

Mr. SCARLETT. All I'm asking is you state what you mean by closing the door. Because Mr. Benson has indicated he does not know what this means or where it comes from.

By Mr. MICHIE:

Q. Do you understand the phrase "to close the door to further pressure from Senator Heinz," do you understand the meaning of that? Do you know what she was getting at?

A. I understand what you just said. I have no way of knowing what she was trying to get at.

Q. I have here from your reference a June 11, 1986 memo to Dr. Henry Desmarais. At that time he was acting Deputy Administrator for HCFA. And this memo was addressed to Commissioner Young.

This memo appears to have represented the Commissioner's comments on a background paper that Dr. Desmarais had shared with him for comments, the background paper to eventually go to the Undersecretary, Mr. Newman. Is that correct, Mr. Benson? Do you have knowledge of any of that?

A. Wait, let me read it.

Q. Sure.

A. OK. I'm sorry, what was the question?

Q. The memo dated June 11, 1986 to Dr. Henry Desmarais, have you ever seen this memo before or were you aware of it in any way?

A. I'm not sure. I may have been. It's vaguely familiar. I didn't author it or I didn't draft it.

Q. You didn't assist in reviewing it?

A. I may have reviewed it. I don't know. It sounds like something that would have come—that would have been staffed out in our office and passed up. I may have signed off on it, I don't recall.

Q. If you would turn to page 2 of the memo, the last bullet, it says: "We are concerned about giving too much weight to our own tri-state survey since its focus is on hemodialysis problems across the board and not solely on reuse."

For the record, I want to point out that the tri-state survey of dialysis clinics involves the States of Ohio, California, and Massachusetts as well as the District of Columbia.

Mr. Benson, do you know why the Commissioner was concerned about giving too much weight to the tri-state survey? Do you know why?

A. No; I don't know why. I would speculate that it was simply with all the emphasis on reuse around this time that we wanted to make sure that it was known that the purpose of the tri-state, studies was not—I mean the tristate studies were not purely reuse. They included reuse, but the emphasis was on the way dialysis was practiced in clinics. That's all.

Q. Do you know whether or not the Commissioner had been made aware that these surveys had in fact uncovered many user related problems in clinics that reuse disposable dialysis devices? Do you know if you had been made aware of that? Have you ever given him a briefing on that, someone from your Center ever talked to him about it?

A. I don't know what's happened in the last couple of weeks because I'be been gone. Prior to that I never participated in a briefing on the tristate studies. Because frankly I've never been briefed on the tristate studies other than, you know, just some across the table type discussions. It's possible that a briefing has been conducted and I'm not aware of it.

Q. Next I'd like to share with you a June 20, 1986 note to Commissioner Young from you in which you alert the Commissioner to the upcoming recall of the infectious ReNew-D as a result of infection outbreaks which as you know infected only a small number of people. On the first page you state:

> It's possible that this case may draw more than it's share of attention. In fact, staff from Senators Heinz's committee are cognizant of this situation.

A. Yes.

Q. Was this not an alert to the Commissioner concerning Senator Heinz's interest in these events, as well as an alert to the situation with ReNew-D?

A. Yes, sure. I mean I'd like—let me put that—let me characterize that exactly as I mean it. I think under normal circumstances I would not have alerted him—I may not have ever been aware myself of this kind of outbreak. I mean there are a lot of problems associated with medical devices, and from a day-to-day standpoint you're not aware of all them. I think it was because of the hearings and because of the Senator's interest. Part of my job is to make sure that—you know, to try to foster good communications. I think he ought to know about that.

So it was both. But I probably would not have sent the memo had it not been for the Senator's interest. Not to say we wouldn't have followed up just as hard on the issue. We would have. From a public health standpoint, we would have done exactly what was done.

Q. Then on page 2 of the memo you go on to state:

> I would ordinarily consider this recall a fairly routine matter in light of the fact that the number of patients involved has been small, but with heightened interest in reuse this may get more attention than it otherwise would warrant.

A. Yes.

Q. Could you define for the record what you consider to be a small number of patients. What are we talking about?

A. If—let's say that there was an outbreak in one or two clinics associated with a given brand of disinfectant, and that it affected, you know, a few patients, I would assume—you know, I would call that a small number. And I would assume that, you know, we would follow up rapidly on trying to figure out the cause of the problem.

If, for example, could be faulty disinfectant, could be faulty handling, could be faulty dilution of the disinfectant. If on the other hand many clinics were involved or many patients from one clinic or one or two clinics were involved, then I would say the flag would go up even harsher, and I would call that many.

Q. A moment ago you mentioned a couple of clinics. By the date of June 20, we have at least five—seven clinics involved, not only with ReNew-D but also the two clinics down in Georgia which involved an entirely different chemical. Do you recall that?

A. Yes.

Q. So we're talking about more than two clinics by the date of June 20.

A. Yes.

Q. So I'm just wondering, how many clinics are you talking about that would cause the FDA to heighten its interest in what's going on and to feel that it warranted attention?

A. I think I've answered your question. In this situation with ReNew-D specifically, I think that would have been handled routinely and I would not have—it may not have even come to my attention. Had it come to my attention, I don't think I would have altered the Commissioner had it not been for the Senator's interest.

Q. Now, OK.

A. So it's not diminishing the importance. It's an important thing and it warrants strong follow-up, which we would have done in either case. I just didn't want the Commissioner to be surprised by something like this by a call from you or someone else.

Q. Which of these two issues at the time were you more concerned about, Senator Heinz's interest or the small number of patients that had been hospitalized, the one patient in Dallas who's death may have been caused by inadequte disinfectant?

A. My priorities are always with public health, absolutely. There's no question about that.

Q. So what you're telling me now is that this memo—I don't want to put words in your mouth, but you weren't intending to minimize the fact that these five or six clinics had these infection outbreaks? Is that a correct understanding on my part?

A. I think it is. I was not trying to minimize. I was trying to portray a recall situation that is routine. If I hadn't said that then the Commissoner might have gotten the impression, any anyone else seeing the memo might have gotten the impression, that this was a major public health flare and media attention and everything else. And that has a lot of—causes an awful lot of problems. And I didn't want to do that.

Q. Do you recall that during the week of June 22 CDC was in the process of drafting an article on the infection outbreaks involving ReNew-D for its June 27 edition of the "Morbidity and Mortality Weekly Report," called the MMWR?

A. Yes, yes.

Q. Did you become involved during that week in discussions with Dr. Marshall or with anyone else at NCHSR, CDC, or FDA regarding the content of that article?

A. Yes, I did.

Q. And when and with whom did you enter into discussions regarding the drafting and prepration of this article? You could take them one at a time to the best of your recollection.

A. We normally did—a staff member that normally interfaces with CDC, and I think she is the one who informed me that CDC was planning to run an article on ReNew-D. We had a recall underway. It was of obvious interest.

I don't remember specifically who it was in the center that I talked to, but applying the philosophy that you talked about a few minutes ago concerning keeping Dr. Marshall informed is the reason that I let him know that this was coming. He had—well, I just thought he ought to be aware of the article.

I'm not even sure whether I actually—I don't remember when I saw a copy of the article. I know that there had been—usually on things like this we try to have as early as possible mutual review of those kinds of article. We usually don't get them much in advance of when they hit the streets. So I can't tell you more specifically.

Q. Did Dr. Marshall share with you the content of his discussions with CDC regarding the article?

A. I don't know that he did directly. I think he did through Eccleston if I recall. I think Bob talked with—followed up on it and talked with him about it.

Q. What was there to discuss about this article?

A. They wanted to make sure that the article was accurate, that——

Q. Is that right?

A. [continuing]. That—it seemed like there were some recommendations for a clinical study and such. And I thought that was a policy issue that Marshall ought to deal with.

Q. Did you agree with the initial recommendation by CDC for clinical trials?

A. I think I recognized that it was counter to agency policy.

Q. And what would that policy be?

A. Well, that additional clinical studies were not warranted or would not have been cost effective.

Q. What is the basis of this, can you tell us?

A. The simple recognition that it's very difficult to separate effects from single use versus reuse.

Q. If you could, tell me who do you think would be in the better position to make decisions on such matters with regard to control clinical study, the FDA or the Center for Disease Control?

A. I think both agencies are qualified.

Q. But in which of those two agencies is reposition the lion's share of expertise in that particular area?

A. Well, I—I think both agencies have a large share of epidemiology oriented people. I always think of CDC as more the detectives, the investigators, the people that, go out and look at a specific issue. I think of FDA as more the clinical trial types who have knowledge of, the review—because we do review clinical trials for both drugs, devices, and so on.

So that's a distinction I make. I think both are fully qualified.

Q. How many epidemiologists do you have on staff, Mr. Benson, in your Center?

A. I don't know off hand.

Q. Well, is it 1, 2, 5, more than 10?

A. Five, five, I believe.

Q. Five? Can you identify these people?

A. I can identify some of them at least. Would you like me to do that?

Q. Please.

A. What's the purpose.

Q. I'm trying to get an idea of the expertise reposited in your agency in order to make decisions with regard to whether or not clinical trials are needed. It's as simple as that.

A. Fine. If you ask me the question about the agency then you're talking about all of FDA and the answere is not five or so. The answer is there are hundreds.

Q. Is this a matter of FDA policy that you identified a moment ago or is it Center policy?

A. No, I think it's PHS policy. And that's why I thought Marshall ought to be aware of it. Because in my view he was the principal person within the Public Health Service dealing with that policy. He had been the spokesman at the hearings, and it was quite appropriate for him to follow up or to be aware. That was the logic.

Q. Now, do you personally have any expertise in the field of epidemiology?

A. I would not consider myself an expert, no.

Q. Then from whom did this policy flow in the way of advice, from your epidemiologists, with regard to your Center or the FDA or the PHS or whomever being opposed to the conduct of controlled clinical studies in the area of reuse of dialysis diseases? From where did this flow?

A. My understanding was that that was part of the heaings, part of the record for hearings. Whether it was in the testimony or whether it was in the discussion, I'm not sure. I wasn't there, I wasn't present at the hearings.

Q. Did Mr. Villforth voice this policy at the hearing?

A. Mr. Villforth, I heard him agree to that policy. Whether he—I don't think he initiated it. I don't know who did. It's my impression—and I can't give you—I can go back and look it up. But I can't give you off the top of my head the source. But my feeling is that is Public Health Service policy.

Q. You say it's your feeling?

A. It's my impression, yes.

Q. Have you and Mr. Villforth ever discussed the matter of policy with regard to whether or not there should be controlled clinical study of reuse? Have you ever discussed this with Mr. Villforth?

A. I recollect, you know, a—not a discussion, but, you know, something along the lines of gee, wouldn't it be wonderful if we could know, you know, with strong statistical validity if there really is a difference between reuse and single use. But beyond that, you know, I don't recall anything. I know that that's kind of wishful thinking.

Q. This question——

A. I think we both recognize—I can't tell you it was from a discussion. But I think we both recognize that in order to do that it would cost a great deal of money and take a great deal of time and become—you know, it's just a difficult thing.

Q. When you say a great deal of money, how much money are you talking about?

A. Hundreds of thousands of dollars at least, may be.

Q. More than hundreds of thousands? Would you say millions?

A. Probably, yes, somewhere on the order of a million dollars.

Q. A million you think?

A. Well, you're asking—I've already said I don't consider mayself an expert, OK, on designing clinical trials. But a study like that, you know, would cost in the ballpark of that kind of money and probably take years to complete.

Q. How many, do you know?

A. I don't want to speculate on that. I don't know. A couple of years or more.

Q. But you do have a policy. The policy is not to conduct controlled clinical studies; is that correct? That's PHS policy?

A. I don't want to make it that strong. I'm under the impression that that's policy, yes.

Q. Who gave you that impression?

A. I don't know where that came from. I thought it came—like I said, I wasn't at the hearings, I though that issue had surfaced. I thought that issue had surfaced. I may be mistaken.

Q. Did you or to your knowledge did anyone else in your center request CDC to make changes in the article as it ws being drafted by CDC?

A. I know we had discussions with CDC. I don't think I personally talked to anyone down there. Basically when I became aware of the issue, I asked our staff to look at it, make sure they had a chance to review the article, make sure that the appropriate people within the center had a chance to look at it to make sure that we weren't tripping over each other. It was that kind of interaction.

And I wanted to make sure that Marshall had the same oportunity. I don't think we had—I don't think we had any major concerns with the article as I recall. But that is not an unusual thing, that is to talk to CDC, to talk about an MMWR article that relates to any product that we regulate.

Q. Did you or did Mr. Villforth advance or approve the changes that CDC was asked to make in the article?

A. I don't think so.

Q. Do you have a definite recollection?

A. I don't have a definite recollection either way.

Q. Let me share with you draft No. 1—and this is a compilation of all four drafts that were generated beginning on the 23d of June. And then of course attached to that is the final version that was published.

A. I'm sorry, what——

Q. OK, now you'll note that there was a facsimile transmittlal to Dr. Villarroel; is that correct?

A. I guess so.

Q. And from whom? Does it say there?

A. Steven Solomon.

Q. Have you ever discussed this matter with Dr. Solomon?

A. No. I don't know Dr. Solomon.

Q. Have you ever discussed this article with Dr. Favero prior to its publication?

A. Dr. Favero.

Q. Favero at CDC?

A. CDC?

Q. Alright.

A. I'm having—I have a very weak recollection of the specifics. You know, I don't recall having a discussion with anyone over it. It's possible that—I know I was concerned about the article hitting the streets without our review. And I know I talked to our own people, and I was putting a fair amount of pressure on them to make sure that we had an opportunity to review it.

I may have talked to Favero. I don't know him either. But the name rings a bell, I don't know.

Q. You raised an interesting point there. You wanted to be sure that you had an opportunity to review this. Why would you be so concerned about this article?

A. Because it was a product that we were in the process of recalling. It's that simple.

Q. Well, what does that have to do with the content of the article?

A. Well, if they were making claims or making statements that were inaccurate, then it would be an embarrassment to both agencies, and has potential for—probably has—well, Tom should answer this, but probably has the potential for litigation. And we just didn't want to go tripping over each other.

Q. Were you able to preclude the CDC from making these inaccurate statements in the article?

Mr. SCARLETT. I object to the question. The witness didn't say making inaccurate statements. He merely said that was one of the purposes of internal coordination is to make sure inaccurate statements are not made.

By Mr. MICHIE.

Q. Let me share with you draft No. 1 if you turn the cover page there, if you will turn to page 3. On page 3 the editorial note, fifth line from the top of the page, which reads as follows:

> There are, however, no control clinical studies validating the safety or assessing the risks of patients in the practice of the reuse of disposable hemodyalizers, nor are there controlled clinical studies comparing the morbidity or mortality of patients being dialyzed with new dialyzers with that of patients being dialyzed with reprocessing or reuse of dialyzers.

If you turn to the draft No. 2, you will find that this statement has been dropped from the article. Did you or to your knowledge did anyone else at FDA or NCHRS request CDC to strike this statement from the article? Do you know if that was one of the editorial corrections or suggestions that was made by anyone at FDA or anywhere else that you know of?

A. I understand the question, but I'm not sure I'm tracking your——

Q. The editorial note on page 3 of draft No. 2.

A. I don't recall if that was one of the things that we were looking at or that was discussed. I don't recall.

Q. Would you have found this—if you were in a position at that time to be reviewing this article for publication, and you of course wanting to give your best advice to CDC to make sure that this was an accurate article, would you have suggested to them that they drop this particular passage?

A. I understand the question, I would like to—I want to read the paragraph.

I think my reaction would have been to alert Marshall to it. I think that I would have been comfortable with his handling it.

Q. To alert Marshall?

A. Yes.

Q. To alert him to what?

A. To the fact that there was an MMWR article coming out that dealt with the use, that dealt with—that spoke of clinical studies.

Q. I understand. But do you find anything offensive or inaccurate about those statements? Do you have information contrary to what is stated there?

A. No; it's not hitting me. I see nothing inaccurate here. It's not hitting me now.

Q. Nonetheless, it was dropped from the article. And you're stating you don't know why?

A. I don't know why.

Q. Turn back now if you would to page 3 of draft No. 1, at the fifth line of the last paragraph. Do you have draft 1 there, Mr. Benson?

A. Yes, I do.

Q. It reads as follows: "There are, however, no Federal standards for insuring the functional or microbiological quality of 'single use only' hemodialyzers reprocessed in hemodialysis clinics."

Now, if you check drafts 2, 3, and 4, you will find that this statement was carried forward in each of them but was dropped prior to publication. Did you or to your knowledge did anyone else in your Center or elsewhere in FDA ask the CDC to remove this statement from the article prior to publication?

A. I don't remember.

Q. I'm sorry?

A. I dont't remember.

Q. You don't recall?

A. I don't recall.

Q. Again, I must ask you, do you have a definite recollection that this did not happen?

A. I don't recall either way.

Q. Is there a way for you to refresh your memory by reviewing whatever papers you might have at your office regarding this question?

A. I would—if I were to go back and double check, I would talk to people that I would have asked to look at it and find out from them if they recall it. I don't have—I know I don't have the stuff in my files because I didn't make the changes myself.

Q. Despite the fact that you don't recall, do you find anything offensive or incorrect or inaccurate with reagard to that particular statement that was dropped prior to publication of the article?

A. Again, let me read the paragraph.

Q. Sure.

A. No; I don't think so. I guess the answer is I'm not sure. I don't know.

Q. You're not sure about what, sir?

A. I'm not sure—I don't know whether there's something wrong with those three lines. I don't have the knowledge in hand that can answer your question.

Q. To your knowledge are there Federal standards for insuring the functional or microbiologic quality of single use only? Do you know? Does FDA have standards?

A. No.

Q. You don't have standards?

A. We do not have standards.

Q. And wouldn't it be safe to assume that CDC epidemiologists who drafted this article would know for certain whether or not CDC itself had these standards?

Mr. Scarlett. I object to the question. It implies a purpose in the deletion of the statement which has not been established. we don't know why it was deleted. They may simply have though that it was repetitive. Without reading the article we can't tell.

Mr. Michie. Thought it was what?

Mr. SCARLETT. They may have thought it was repetitive. they may have thought it was written in bad English. Your question assumes a purpose. If the witness answeres the question as posed, he will assume the purpose. That purpose has not been established. I object to the question on that basis.

Mr. MICHIE. You objection is duly noted. And it will be referred to the Chairman for disposition.

Mr. SCARLETT. OK.

By Mr. MICHIE.

Q. I'd now like to share with you a one-page memo dated April 16, 1986—before we get to that, before we get to that, let me just finish with this memo.

This regards the CDC article. This is a memo dated June 25, 1986. It's a memo to the Commissioner signed by James S. Benson. And if you will pass this copy over to Mr. Benson.

Mr. Benson, I would like to call your attention to the third paragraph on the first page of this memo. "We've been told that CDC plans to release the article this Friday. A copy of the latest draft is enclosed at tab B. Our staff have been in contact with both the authors of the article and reviewing officials to suggest some changes to bring it in line with the statements about dialysis reviews made by Dr. John Marshall and John Villforth at the congressional hearings on this subject this past March."

Now, my question is what did you mean when you stated that your staff suggested changes to bring the article in line with statements about dialysis reuse by Dr. Marshall and Mr. Villforth? What did you mean by that?

A. The same thing I said a few minutes ago, that—when Marshall and Villforth make statements at the hearing as far as I'm concerned, that's stating a policy, Public Health Service policy. I think that it's proper that CDC, you know, at least if they are going to publish an MMWR article or anything else, that if it's not in concert with that, then at least a discussion ought to be held.

That was the point of this statement. It's what I said a few minutes ago.

Q. Did the CDC bring its article into line with what Dr. Marshall and Dr. Villforth stated at the hearing; do you know?

A. I don't honestly know. The issue was not that big an issue to worry that much about. I didn't even follow up on it. I don't even know that I read the final article. It was—it was my attempt to do proper intra-PHS coordination. It was that simple.

Q. You just stated that you didn't think it was that important or it was not really important enough. Why then would you make this statement to the Commissioner? Surely you don't put unimportant matters into memos to the Commissioner; do you?

A. I try not to.

Q. Did you——

A. I'm giving you a straight answer. I didn't follow up on the final article to see whether they made any changes or not. I simply don't know. I was satisfied that I had surfaced the issue, didn't feel any need to go any further on it.

Q. Did Mr. Eccleston or did Dr. Villarroel or did Nurse Reid or did anyone on your staff report to you following or just prior to publication of the MMWR that it had been changed, edited, whatever term you want to use, to their satisfaction?

A. I don't recall a report. I do recall having a final draft and saying this is what they are going with. And I don't—you know, that's the extent of my recollection.

Q. Now, if we can go back now to that——

Mr. SCARLETT. Can we go off the record?

Mr. MICHIE. Pardon.

Mr. SCARLETT. Could we go off the record?

Mr. MICHIE. For what purpose.

Mr. SCARLETT. I want to ask you a question about how long this is going to last.

Mr. MICHIE. I'd say approximately 5 minutes longer.

Mr. SCARLETT. Thank you.

Mr. MICHIE. You're welcome.

I'm sorry, Mr. Benson, did you have a comment?

The WITNESS. It was a joking comment, no comment.

By Mr. MICHIE.

Q. If you would now refer to that one-page memo that we handed to you dated April 16, 1986, to the Secretariat from Dr. Macdonald, who was then the Acting Assistant Secretary for Health, the memo advises the Secretary on how the FDA believes it should respond to the Heinz March 21 letter to the Secretary, in which the Senator urged that the FDA's good manufacturing practices, GMP's, regulations, to be imposed on reprocessors of disposable dialysis devices. Have you seen this memo prior to coming here today?

A. Can I read it?

Q. Sure.

A. The atmosphere here is not real conducive to concentration. So bear with me a minute.

Q. Please.

A. No: I don't recall seeing that.

Q. If you would please take note of the third paragraph where—it's a one-page memo. And Dr. Macdonald states and I quote:

> FDA believes the response to the Senator should state that dialyzer reuse is exempt from FDA regulations. FDA's General Counsel has concluded that a legal argument can be made either way, imposing GMP's or not.

Were you aware at that time that your own general counsel believed that a legal argument could be made for imposing GMP's or not for imposing them and that therefore it was a matter of policy decision on the part of the Department? Were you aware of that?

A. Well, my impression has always been that the legal argument is arguable, that it's arguable, I think I said that earlier. So that has been my impression in terms of the first part of your question. You asked me also therefore is it——

Q. A policy decision? If you can argue it both ways. An argument can be made either way—correct me if I'm wrong because general counsel is sitting here, Mr. Scarlett—then it's a matter of policy; is it not?

A. You can state it that way sure. I think that—well, I don't want to belabor it.

Q. Please go ahead if you want to add something.

A. Well, if there were a clear-cut legal position, then the decision would be much simpler—I'll wait until you're finished.

Q. No, go ahead. I'm listening.

A. If the legal position is not clear, no matter which direction we go, then we're apt to get bogged down in some kind of litigation. So I don't call that a policy issue. But if you want to call it a policy, that's fine, I can accept that.

Q. But we're talking about a memo—and you can read it right there—it states in there that.

> FDA believes the response to Senator Heinz should state that dialyzer reuse is exempt from FDA regulation. FDA's General Counsel has concluded that a legal argument can be made either way, for imposing GMPs or not.

A. Right.

Q. So it's a matter of policy; is it not? It's a policy decision?

A. I don't characterize it that way. You know, it's not——

Q. Well, now, if the general counsel were to characterize it that way, would you accept it?

A. If counsel said this legal decision is arguable, therefore why don't you make the decision based on policy, then I would accept it.

Q. We are—at the present time we're locating the attachment to that memo. And the attachment to that memo is a briefing paper put together by the General Counsel's Office of FDA. And in that briefing paper it states perhaps a little more clearly than is stated in the memo, it says: "Therefore, it is a policy decision."

A. OK.

Mr. SCARLETT. I don't think we need to get the attachment. Mr. Benson has already stated that he would accept it.

Mr. MICHIE. All right. I'd like to show this to you for your own satisfaction. If you would, Mr. Scarlett.

Mr. MICHIE.

Q. Under the heading "Concerns," would you read that aloud for us please.

Mr. SCARLETT. I'd like to note for the record that this is not prepared by the general counsel's office. It's a characterization of somebody's understanding of what the general counsel's view is.

Mr. MICHIE. Perhaps you would care to give us your opinion, Mr. Scarlett, as general counsel. Is that a fair characterization of the opinion of your office or not?

Mr. SCARLETT. I will not answer the question. I'm clarifying that for the record only.

Mr. MICHIE. Would you not tell us as to whether or not that's a fair characterization of your office's opinion?

Mr. SCARLETT. I will not tell you, that's correct.

Mr. MICHIE. Why not?

Mr. SCARLETT. Because I'm not here to testify.

Mr. MICHIE. We know that. But in the spirit of cooperation you could clarify this for us.

Mr. SCARLETT. Well, I could if I was down here to cooperate. But I'm here to advise my client, Mr. Benson.

Mr. MICHIE. This deposition is in recess until further notice. The witness is subject to recall. Therefore the record is left open at this point, but at the same time the transcript of this proceeding will be sealed until further notice.

Thank you, gentlemen.

[Whereupon, at 4:55 p.m., the taking of the deposition was concluded.]

UNITED STATES OF AMERICA

Congress of the United States

To James S. Benson, Deputy Director, Center for Devices and Radiological Health, Food and Drug Administration, U.S. Public Health Service, U.S. Department of Health and Human Services,

Rockville, Maryland, **Greeting:**

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* September 3, *19*86, *at* one *o'clock* p.*m., at their committee room* SD-G33 in the Dirksen Senate Office Building, *then and there to testify what you may know relative to the subject matters under consideration by said committee,* in sworn deposition to be conducted by committee staff.

Hereof fail not, *as you will answer your default under the pains and penalties in such cases made and provided.*

To James F. Michie, Chief Investigator,

to serve and return.

Given *under my hand, by order of the committee, this* 14th *day of* August, *in the year of our Lord one thousand nine hundred and* eighty-six.

John Heinz

Chairman, Committee on Aging

UNITED STATES OF AMERICA

Congreſs of the United States

Notice of
Senate Deposition

To James S. Benson, Deputy Director, Center for Devices and Radiological Health, Food and Drug Administration, U.S. Public Health Service, U.S. Department of Health and Human Services,

Rockville, Maryland *Greeting:*

Please *take notice that at* one *o'clock* p.m., *on* September 3, *19* 86, at Rm. SD-G33, Dirksen Senate Office Bldg., Washington, D.C., J.F. ~~at~~ Michie, D.G. Schulke & C.C. Jennings, *of the staff of the* Special *committee on* Aging *of the Senate of the United States, will take your deposition on oral examination concerning what you may know relative to the subject matters under consideration by said* Special *committee. The deposition will be taken before a notary public, or before some other officer authorized by local law to administer oaths; it will be taken pursuant to the* Special *committee's rules, a copy of which are attached.*

Given *under my hand, by authority vested in me by the* Special *committee, on* August 14, *19* 86

John Heinz

JOHN HEINZ
Chairman

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

John C Villforth

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this 23rd day of September, 1986, and executed the above certificate in my presence.

Kay A. Levin
NOTARY PUBLIC IN AND FOR
State of Maryland
County of Montgomery

MY COMMISSION EXPIRES: July 1, 1990

THURSDAY, SEPTEMBER 4, 1986

Washington, DC.

Deposition of John Villforth, called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 1:12 p.m., before Cathy Jardim, a notary public in and for the District of Columbia, when were present on behalf of the parties:

Appearances:

For the Special Committee on Aging:

James F. Michie, chief investigator.

Christopher Jennings, professional staff member.

Michael Werner, committee legal counsel, Special Committee on Aging, U.S. Senate, room SDG-33, Dirksen Senate Office Building, Washington, DC 20510.

On behalf of the deponent:

Thomas Scarlett, Esq., chief counsel, Food and Drug Administration, room 6-57, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Mr. MICHIE. Good afternoon. My name is James Michie. I am chief investigator of the Special Committee on Aging of the U.S. Senate.

Present with me in SDG-31 is committee counsel Michael Werner, committee staff member Christopher Jennings, the notary public and stenographer Cathy Jardim, and Mr. John Villforth, Director of the Center for Devices and Radiological Health in the Food and Drug Administration, U.S. Public Health Service.

Mr. Villforth is accompanied by Thomas Scarlett, general counsel for the Food and Drug Administration.

On August 29 Mr. Villforth was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging, for the purpose of being deposed by committee staff on this 4th day of September 1986. A copy of the subpoena and notice of deposition will be made a part of this deposition record as exhibits 1 and 2 respectively.

Prior to being sworn in, Mr. Villforth, I want to remind you that if you knowingly provide false testimony under oath you may be subject to prosecution for perjury.

Are you ready to proceed?

The WITNESS. Yes.

Mr. SCARLETT. I have a statement for the record.

I am Thomas Scarlett, chief counsel for the Food and Drug Administration. I have been designated by the Department of Health and Human Services to accompany John C. Villforth to this interview.

The Department has asked me to indicate it is volunteering to make Mr. Villforth available in order to cooperate in an investigation of issues relating to dialyzer use and that Mr. Villforth is participating solely on that basis. He has been advised by attorneys for the Department that the subpoena recently served upon him is of doubtful legality and that the Department does not regard his participation to be compelled by the subpoena or governed by its terms. Nevertheless, subject to this understanding he is prepared to answer any questions you may have.

An issue has arisen as to the authority of the court reporter to administer the oath to witnesses. While the Department continues to believe that under the standing rules of the Senate only the chairman of the committee has the authority to swear in a witness, in order to cooperate and to get to the substance of issues concerned, Mr. Villforth will cooperate without conceding to it any legal significance it does not otherwise have. In so doing Mr. Villforth has asked me to emphasize that whether or not sworn he would answer truthfully to the best of his knowledge. That is it.

By Mr. Michie.

Q. Are you acquainted with the chairman's rules regarding the validity of the subpoena as well as the validity of the oath?

A. Yes.

Q. How did you come to be familiar with those rulings?

A. The August 28 letter to Mr. Reisberg was circulated to me but I had seen it prior to that.

Q. I want to remind you once again that if you knowingly provide false testimony under this oath, you may be subject to prosecution for perjury.

Are you ready to proceed?

A. Yes.

Mr. Michie. Would the notary public please administer the oath to Mr. Villforth.

Whereupon, John Villforth was called for examination and having been first duly sworn was examined and testified as follows:

EXAMINATION BY THE CHIEF INVESTIGATOR FOR THE SPECIAL COMMITTEE ON AGING

By Mr. Michie.

Q. Would the witness state for the record his full name, age, and home address?

A. John C. Villforth. I live at 7200 Wapello, W-A-P-E-L-L-O, Drive, Derwood, MD, 20855. I am 55 years old.

Q. With the exception of your having received appropriate and necessary advice and counsel from your attorney regarding your rights as a witness in this deposition, has anyone prior to your appearance here today attempted to influence in any way your testimony in this deposition?

A. No.

Q. Prior to your appearance here today have you discussed with Mr. Benson his testimony and deposition yesterday?

A. Yes.

Q. Tell me why did you discuss his testimony?

A. We discussed for about 3½ minutes last night the fact that he was here, basically what went on and I suggested that he go to bed.

Q. Prior to your appearance here today you were requested to bring with you your appointment calendars for 1986. Do you have these with you?

A. I do not.

Q. Are you a Public Health Service officer?

A. I am.

Q. And what is you rank and for how long a time have you served?

A. I have been in the Public Health Service since 1961. My rank is O8 rear admiral.

Q. Briefly, if you will, what is your academic and training background, Mr. Villforth?

A. I have a bachelors degree and masters degree in sanitary engineering, and a masters degree in physics.

Q. For the sake of saving time today, we will during the course of this deposition refer to your agency as the FDA; the Center for Devices and Radiological Health as the Center; the National Center for Health Services Research as NCHSR; the Centers for Disease Control as CDC; the National Institutes of Health as NIH; the Health Care Financing Administration and HCFA; the Public Health Service as PHS; the Department of Health and Human Services as the Department.

Is that satisfactory with you?

A. Yes.

Q. Could you briefly describe the function and mission of the Center, your Center?

A. The Center is responsible for implementing two pieces of legislation, the Medical Device Amendments of 1976 and the Radiation Control for Health and Safety Act of 1968. As such we provide the focal point within FDA for programs that are related to medical devices, all aspects of medical devices, the introduction of those devices on to the market, its assurance that those devices are manufactured safely through good manufacturing practice, the monitoring of trends and problems of those devices through various mechanisms and the institution of various educational programs that are needed to solve problems that are associated with the risks of those devices.

And the Radiation Control for Health and Safety Act, basically, we implement the provisions of that act which specifically state that we are to protect the public health and safety from unnecessary ionizing and nonionizing radiation produced by electronic products such as lasers, ultrasound, x rays, et cetera. We do that by implementation of regulatory performance standards and inspect against those performance standards and we do have various educational programs directed at the profession, technologists, consumers, to try to minimize the consequences of the use of those radiations and thus the radiation exposure of the population.

Q. For how long a time have you served as Director of the Center?

A. The Center was formed in 1982 out of two separate bureaus, the Bureau of Medical Devices and the Radiological Health Bureau. Prior to that I was a Director of Radiological Health since 1969.

Q. Who is your immediate superior?

A. The Commissioner of the Food and Drug Administration.

Q. Are you not reporting to the Deputy Commissioner—through the Deputy Commissioner?

A. I don't think so. On some matters I report to him as it relates to certain issues but basicallay I report to the Commissioner.

Q. As a rule you report directly to the Commissioner?

A. That is correct.

Q. Have you ever received instructions or assignments regarding your duties and responsibilities as Director of the Center from anyone above the Commissioner in the PHS chain of command?

A. No.

Q. For how long a time has your Center been involved in an effort to formulate a policy on the reprocessing and reuse of disposable medical devices, not just dialysis?

A. For some years. I don't know when the initiative was first started.

Q. Was it started prior to your becoming Director.

A. It was started prior to when I was Director.

Q. When you came on as Director who at that time was given primary resposibility for this effort, and that would have been in 1982, correct?

A. In 1982, yes. The responsibility probably was at that time, to the best of my recollection, the Office of Training and Assistance, OTA.

Q. Who in that office?

A. Probably Larry Kobern. I am not sure if he was in that office initially so I can't remember how it started out.

Q. Who has that responsibility now?

A. The Office of Traning and Assistance.

Q. Who in that office?

A. I think we look to Larry Kobern.

Q. Did he have that responsibility on March 6 of this year?

A. We look to him for that responsibility.

Q. Do you recall him having that same responsibility in 1983?

A. I think he did.

Q. 1984?

A. I assume he did. I don't know. I assume there was continuity. I can't remember specifically when he started and all the details.

Q. How high a priority had you assigned to this effort when you came on as Director?

A. I didn't assign any high priority to it other than—I assigned no high priority to any of the items. It was an attempt—we had various task forces looking at a variety of issues, sterilization, good manufacturing processes, to try to help us decide which is the better way to go. It wasn't a matter of deciding, wow, this is a good way to go. We don't have those kind of numerical listings. We are in the process of doing that but we haven't got that started yet. We are just at the point of assigning numerical values. At that time we didn't and therefore I can't give you a figure as to what the priority might be. There was obviously concern as there is for sterilization, and good manufacturing process, et cetera, et cetera.

Q. Do you recall the priority for this particular policy development having been upgraded in recent years?

A. On reuse?

Q. On reuse, by the reuse committee as per instruction from the senior staff?

A. There was increased concern at some of the Center meetings that we ought to pay more attention to that issue. We did cosponsor a meeting with the Georgetown University on the whole question of reuse, yes.

Q. What is you estimate at this time for——

Mr. SCARLETT. May I request a brief recess? I need to consult with my client?

Mr. MICHIE. Of course, We are in recess so that the depondent may consult with his attorney.

[Discussion off the record.]

Mr. MICHIE. Back on the record.

The WITNESS. There may be some question that I may not have understood the question correctly and I would ask if you could repeat that because I may have been confusing reuse and dialysis reuse.

By Mr. MICHIE.

Q. The one about how high a priority you had assigned when you came on to this effort to develop a policy?

Mr. SCARLETT. No, the one immediately preceding that, about has the priority been upgraded.

By Mr. MICHIE.

Q. Since you have come aboard——

Mr. SCARLETT. Can we have the question restated?

Mr. MICHIE. Can you do that for us?

[The Reporter read the requested portion of the record.]

By Mr. MICHIE.

Q. Did you not understand that I was asking the question with regard to the development of the policy——

A. Of reuse or——

Q. Reuse. We are still on reuse. We are not on dialysis yet. Reuse of disposables?

A. If I interpret your question you are saying has the Center placed increased interest or emphasis on reuse across the board——

Q. On developing policy with regard to the reuse and reprocessing of disposable devices, medical devices?

A. And the answer is yes, the Center has paid increased attention as indicated by the sponsorship of the Georgetown conference.

Q. When was this higher level of priority placed upon this particular development of policy?

A. I think probably as a result of the Georgetown conference and the discussions that led up to the Georgetown conference where this was indicated by the people that participated in this, that there were technical, scientific, legal issues.

Q. What year was that, do you recall?

A. No, I don't.

Q. Could it have been 1982?

A. Could have been, yes.

Q. What is your estimate at this time for finalizing this policy?

A. I don't have an estimate. I can't tell you that right now.

Q. Not even a curbstone estimate, months, years, can you at least tell us that, some idea?

A. It probably will be months, but I can't give you an estimate.

Q. Less than a year?

A. I can't give you an estimate.

Q. Could it be over a year?

A. It could be.

Q. So it could be years?

A. It could be a year.

Q. Or two?

A. I told you what I said.

Q. You said it could be a year?

A. Could be a year.

Q. Could it be two?

A. It could be two.

Q. Within this effort to formulate this policy, how high a priority have you assigned specifically to formulating policy for the reprocessing and reuse of disposable dialysis devices?

A. Within the framework of that policy how high a priority have I assigned to reuse of dialysis? As I told you before, we don't have a value for priority and therefore I don't know how to answer the question in terms of whether it is a 1, or a 10, or a 3.

Q. As far as importance to you as the Director, is the policy for this category of devices on the same level of importance as for other medical devices?

A. I think from a public health standpoint, it is perhaps no more important than the other devices that we are dealing with. It certainly has, because of the Senator's concern, been given a considerable amount of notoriety which had increased our awareness of the need to develop action programs but I am not sure from a public health standpoint, in terms of the consequences, that it is any different that the rest of reuse.

Q. You mentioned a Senator, which Senator would that be?

A. I am referring to Senator Heinz and the hearings he has been having.

Q. Is it FDA's intention to first formulate policy for a dialysis category of disposables or to all at once formulate overall policy for all disposables? In other words, do you intend to separate out the dialysis or will it all come at once?

A. I don't think we have made a decision as to which will come first or second.

Q. Are you entertaining such a suggestion?

A. We will listen to all the comments and suggestions we can get. As I just told you I don't think there is necessarily a feeling of the difference of the public health consequence of that dialysis vis-a-vis the reuse of other medical devices and their public health consequence.

Q. What I am trying to get at is it not the case that in recent years there has been discussion with regard to separating out these dialysis disposables and developing policy for them first of all? Has there not been discussion about that?

A. I think there has been discussion about that.

Q. And you have been involved in that, haven't you?

A. Yes.

Q. Has there been any movement in that regard or are you still in discussions?

A. We are still in discussions.

Q. Did you attend a meeting of a task force earlier today?

A. Yes; I did.

Q. What is the name of the task force and who was it established by?

A. It was established by the Assistant Secretary for Health, Dr. Windom, and the title of the task force is task force on Kidney Dialysis Reuse, I believe.

Q. What was the purpose for Dr. Windom establishing this task force?

A. Basically to address the recommendations that were presented by John Marshall's report to Dr. Windom, the attached two-page recommendation to the main report that Dr. Marshall prepared for Dr. Windom in which certain assignments of responsibility were given to the NIH, FDA, CDC.

Q. And the report you are referring to is the report on the Health Techonology Assessment that was recently completed by NCHSR. Is the correct?

A. That is correct.

Q. What tasks were you assigned at this meeting?

A. At this meeting or in the recommendations?

Q. At this meeting. Were there any assignments at this meeting?

A. Yes; there were assignments given to ask which of the—we went over the recommendations with the idea that at the next meeting we would have a lead person discuss each of those recommendations and present arguments and the understanding was that the lead person, or in this case, agency, would not necessarily have to agree with the positions, but rather use these—take the lead as a discussant and I was given the responsibility to talk about the two items roman numeral III A and B, I think you would refer to in the recommendations.

Q. In the recommendations?

A. Yes.

Q. From NCHSR?

A. Yes

Q. Can you give us some idea as to what those are?

A. One has to do with the good manufacturing practice.

Q. The imposition of GMP's?

A. The imposition of good manufacturing practice on dialysis centers.

Q. And the second?

A. The second one had to do with the recommendations that would be provided to HCFA for them to consider in implementing inspectional programs for reuse. The limitation of my discussant would only be those related to reuse. CDC had the lead in responding to other recommendations to HCFA on basic dialysis. Those two were assigned to me. There was other responsibility that was originally in the recommendation by Dr. Marshall which had to do with standards for reuse, questions of flowthrough pressure and so forth, and that was decided that it would probably be better handled by the National Institutes of Health.

I also volunteered to be the discussant leader next week for the session on education, what kind of educational activities should we present.

Q. What was the recommendation with regard to GMP's, do you remember?

A. Basically it said that the—yes, I should remember—it said the Department would implement GMP's, was the recommendation.

Q. The recommendation was to——

A. Recognizing that these recommendations did not flow from the text, to the best of my recollection. They are not part of the text. They are separate recommendations. There is no supporting documentation or even elaboration. They are presented in the form of an outline.

Q. Would that not be found in the report itself?

A. I doubt it.

Q. Why would you doubt this?

A. I couldn't find it.

Q. You can't find a recommendation or any discussion whatsoever——

A. I can't find the recommendations that would lead up to the conclusion that we should apply the GMP's. There is a discussion on the GMP's.

Q. What you are saying is you can't find anything in the report that supports the recommendation to impose the GMP's?

A. That is correct.

Q. Was this the first meeting of the task force?

A. Yes, it was.

Q. Who chairs this task force?

A. Mr. Jim Freedman.

Q. What is his position?

A. He is the deputy to Mr. Grossman who is the chief planning officer.

Q. Is he on——

A. Windom's staff, yes—planning and evaluation.

Q. Can you just, if you can, tick off the names of the other members of this task force?

A. They are in my briefcase. I have forgotten them.

Q. That is all right. We can find that out later.

A. You can be sure——

Q. There is representation from all of the agencies involved, NIH, FDA, NCHSR, HCFA, CDC?

A. The three main agencies were always on the task force. They just added NCH—the parent organization, Marshall's organization.

Q. National Center for Health Services Research and Health Technology—Health Care Technology Assessment?

A. Thank you. Right, Dr. Marshall. And they have added general counsel to that. Not all of the elements of PHS are there. HRSA is not there.

Q. Are there any milestones set for this group?

A. No. That is a subject that will be coming up as a result of the discussions that will take place next week. The idea is to get things wrapped up as quickly as possible. I mentioned to the chairman, since they knew I was coming up here for the disposition, that I would probably be queried on this and they wanted to reassure you that they would be up here and assure you they would be telling you firsthand. If you want to find out, you will hear it firsthand. They are well aware of the Senator's interest and your interest so they intend to be fully cooperative and provide you firsthand knowledge.

Q. Did anyone at today's meeting suggest or indicate that it was time to quit playing politics on the reuse issue and time to get on with what needs to be done? Did anyone indicate or suggest that in so many words?

A. They may have. I don't recall.

Q. They may have?

A. That is what I said.

Q. Can you recall who might have said that?

A. No.

Q. Could it have been Mr. Freedman?

A. I said I couldn't recall. That didn't seem to be a particularly exciting or alarming statement and if it was said, I wouldn't have particularly felt it was noteworthy of recollection.

Q. Did you receive a copy of the briefing materials that were provided to the Department's policy council for its meeting on August 27 of this year?

A. No—is that the last—well, I don't know. I don't think so. The last policy council that I know that it was reported this was discussed at?

Q. August 27.

A. Is that the last one? I was not aware that that took place. I did not know who the FDA representative was, if there was a representative there. I don't know if it was the Commissioner. I was not aware that this subject came up and was rather surprised that it was even presented.

Q. Are you aware that these briefing materials state that CDC believes that there is a need for additional clinical studies to determine the safety and efficacy of reuse of disposable dialysis devices?

A. I received the—to answer your question, I have not read the CDC's response and I assume you are asking the question do I know the CDC responded in this way to the request by Dr. Windom to comment on the Marshall recommendations.

Q. No. Let me make myself understood. What I am asking about is if you didn't see these briefing materials or have—someone might have discussed them with you, so I asked you if you were aware that these briefing materials state that CDC believes that there is a need for additional clinical studies to determine the safety and efficacy of reuse?

A. No one discussed that with me. We did get a hand out today and we just paged through it. I did not have a chance to read it.

Q. I will share with you a copy of the briefing materials that were provided at that policy council meeting and I will ask you to turn to page 5. They are numbered at the bottom of each page. I will ask you to read aloud if you would the last sentence.

A. Studies on reuse have generally been either retrospective or of a nonclinical nature. MMWR recently agreed that there is additional need for clinical studies to study the use and reuse of human dialysis.

Q. Is this the first knowlege that you have had of the fact that CDC does, in fact, recommend clinical studies?

A. Well, I don't know that—this piece of paper, which is undated and unidentified, and which has words on it, which I just got through reading—if in fact this is CDC's document—I can't indicate—I can't support the fact that this is what their position is other than they said this same statement in the MMWR so I don't think there is any revelation in here.

Q. So it wouldn't surprise you?

A. They made that same sort of statement in the MMWR, I believe.

Mr. SCARLETT. I would like to note for the record that Mr. Michie has not laid any foundation for the introductory use of this document. If this were a court proceeding it probably would not be capable of being introduced or used, whether or not it is admissible. I am sure Mr. Villforth will do his best to comment on any statements you would like him to comment on but I don't think we can provide you with the credentials for these documents. It might be useful if you could.

The WITNESS. I don't know whether you——

Mr. MICHIE. I would be delighted to have——

Mr. SCARLETT. If not the credentials then at least the background of your understanding of what this is.

Mr. MICHIE. These are briefing materials that were provided at the August 27 meeting of the policy council.

Mr. SCARLETT. But the document does not contain any identification as to its source.

Mr. MICHIE. If you turn to page 1, what does it state?

The WITNESS. Briefing for the Under Secretary's Policy Council. Is that what you mean?

Mr. MICHIE. Yes.

Mr. SCARLETT. The question is who prepared it. There is no statement on page 5 that the CDC has stated that it is making a recommendation with respect to clinical investigations. It refers to the MMWR which is a CDC publication. It is all rather nebulous.

Mr. MICHIE. We will be happy to make a copy of that so you can take it back with you, Mr. Scarlett, and confirm as to whether or not these were materials presented to the policy council. Would that be satisfactory to you?

Mr. SCARLETT. I think you are misunderstanding the point——

Mr. MICHIE. No; I am not at all. You are doubting the validity of this document.

Mr. SCARLETT. No, I am not. We cannot characterize the document because Mr. Villforth was not at the meeting, and neither was I and the document does not contain any information about who wrote it.

Mr. MICHIE. I didn't ask him to characterize it. I asked him to read the last statement on page 5.

Mr. SCARLETT. And then you said is this the first inkling you had whether CDC was making the recommendation. Mr. Villforth said he didn't know because we have a piece of paper that does not have an identification origin. Maybe if we were given a little bit of time we could figure out where it came from and Mr. Villforth could respond more usefully.

Mr. MICHIE. Does that satisfy the record as far as you are concerned?

Mr. SCARLETT. Yes; it does.

The WITNESS. Could you go back and rephrase the question? The question was with regard to that statement. Help me—replay that question.

By Mr. MICHIE.

Q. You may very well be recalled for additional testimony and I think what we should do is prior to your going back to restate your answer, that we should provide whatever information or clarification is needed to you and to your lawyer. OK?

A. Yes; but I think you misled me and that is why I would like to offer the opportunity to comment on it. You left me with the impression that this was the CDC's statement because it was a CDC document but it is under the section—it suggests it is an attachment.

Q. I did not identify that as a CDC document. The first page identifies itself. These are materials, as I stated earlier, that were presented at the policy council meeting. Now, if you read the last sentence, as you did in the record, I didn't suggest anything about the validity of it. You read the last sentence and if there is any question, and there obviously is, about the origin of this document or whether in fact it was given out at this policy council meeting we will settle that for the record.

Mr. SCARLETT. I don't agree that nothing you said related to the validity of it. The question you asked was, was this your first information that the CDC was taking this position. The question implies an assumption of validity.

Mr. MICHIE. Then he responded that he had read the MMWR—isn't that what you said?

The WITNESS. YES.

Mr. MICHIE. Obviously it wasn't the first time he saw it.

Mr. SCARLETT. We are quibbling over the inessentials. The essential point is it is very difficult for Mr. Villforth to give you a useful reaction to a document when you hand it to him and it has no identification, and he does not have time to read it and digest it fully.

By Mr. MICHIE.

Q. Would you like a copy?

A. Yes.

Q. Yesterday, Mr. Benson stated in his deposition that it has been the policy of FDA to impose clinical trials on reuse. Was he correct, is that the policy of FDA?

A. I don't know what he said, but is the question of imposing clinical trials?

Q. Right, of feeling that there was no need——

A. If somebody wants to do clinical trials we wouldn't oppose them. We wouldn't think from an FDA standpoint they would be very effective. Probably Mr. Benson would have explained to you the problem with clinical trials is the difficulty of the patients you are dealing with. It is very difficult because these are sick people to do clinical trials. You don't have good controls, you don't have good exposed population and it is not an effective way of doing business. If some one would want to do that, it is unlikely that FDA would raise its hand and say, it is dumb, don't do it. We would not do that because it is very costly.

Q. And time consuming?

A. That is right.

Q. And you stated to Senator Heinz at the March 6 hearing, page 92 of the hearing record, "The ideal way to do things is under controlled clinical studies but those take time."

Do you recall that?

A. Yes.

Q. Is the matter that such studies take time the primary basis for FDA's policy to not want to have them conducted?

A. I don't think that FDA's policy is not to want to have them conducted. I think the problem is it is very difficult in terms of dollars and time and the questionable outcome because you are dealing with—in order to do good clinical trials you need to have a population under study and a controlled population and when you are dealing with people as sick as these are, with this kind of disease, it is very difficult to do the kind of controlled clinical studies that one would do in many of the other areas of medical devices and drug research. I don't want you to leave anybody with the impression that we are opposed or fighting someone from doing that.

Q. I am not suggesting that at all.

A. The innuendo was that.

Q. I am not suggesting that and there is no innuendo attached to this. I am trying to find out whether or not FDA would object to doing clinical studies on its own and a moment ago you answered my question and said no.

A. Right.

Q. Does FDA continue to—pardon me. Have you or anyone on your staff discussed this particular issue with CDC?

A. The question of clinical trials?

Q. Yes, the question of the need for clinical trials?

A. I have no idea whether the staff has. I have not discussed it. I can't speak for the staff.

Q. Are you a member of the senior staff at the Center?

A. Yes; the most senior and I intend to remain there.

Q. Let me share with you, October 23, 1984, report of the Dialysis Use Committee which, according to Dr. William Dierksheide, his cover memo was submitted to the senior staff, and I presume to you as well, of your Center. Do you recall this report and its findings?

A. Not really. I am aware of its existence.

Q. When did you become aware of its existence?

A. I am sure after—I can't tell you when.

Q. Do you think it would have been submitted to you along with the rest of the senior staff?

A. It said it went to the senior staff so I assume it did.

Q. Can you recall reviewing that document any time within the past several months?

A. No.

Q. To your recollection you are looking at the document now and you don't recall ever seeing it before?

A. I don't recall ever seeing—I don't specifically recall seeing it before but I am sure I did.

Q. We learned yesterday from Mr. Benson of the existence of the Dialysis Use Committee and that it operated concurrently but separate and apart from your Reuse Committee which has been striving since the summer of 1983, I believe, to formulate a reuse policy. Was the Dialysis Use Committee established at your direction?

A. I don't remember that I directed it to be done. I think it was something that was recognized that there was a need within the Office of Training and Assistance. It developed that way. I don't know that I went out and said do it.

Q. Do you recall the purpose of this group?

A. The purpose of this group was to try to do a literature search to try to better understand the problems associated with dialysis across the board and to pull together the literature that would identify whether there were problems with dialysis across the board. It is my understanding that some of this was a predecessor to the State contracts, the understanding of this led to some of the State contracts which suggested some more data was needed.

Q. Are you aware that this report contains 39 pages of user related problems and elaborations, including accidents, injuries, malfunctions, potential and serious hazards associated with dialysis and the reprocessing and reuse of disposable devices, poor quality control, and bacterial contamination of these devices as well as the water used in reprocessing?

A. I was aware that this report contained them. I don't know about 39 pages.

Q. You can count them.

Was the knowledge ever shared with anyone outside your Center prior to my having reviewed it on August 29, 1986, at the FDA?

A. Not to my knowledge. There is no reason that it wouldn't have been but I can't say.

Q. Was it ever shared with the Commissioner or anyone in his office?

A. Not to my knowledge.

Q. Did your Center ever, prior to or during the NCHSR assessment of dialysis device reuse, share this report with anyone at NCHSR?

A. Not that I know of.

Q. Do you think it should have been?

A. It wasn't directed to the question of reuse. It was directed to the question of kidney dialysis across the board and the indications were that it wasn't—it was rather equivocal and although there was need for attention based on the next step of going to the State contracts, I don't think there was particular revelations there.

Q. But it did include information regarding problems with reuse, did it not?

A. I think there were reuse problems in there. I don't know if all of these—whether you could separate the use from the reuse problems. This is always one of the difficulties, whether it is a use or reuse problem.

Q. Do you think this might have been useful in light of the fact that it does contain information regarding reprocessing and reuse—do you think it might have been useful for the NCHSR to have this report in its assessment?

A. The answer, of course, that you are looking for is, yes; it would have been useful and therefore to show that we failed in failing to provide that report. I don't think it was that useful. However, I think we should have given it to them so as to avoid the embarrassment. It is very important to have negative data or different data so you can put it in perspective. From that standpoint—I don't think there is anything in here that would be earthshaking to them or change their recommendation.

Q. Would it not have been appropriate for them though, for the staff at NCHSR to make that decision, once you provided that to them?

A. To make the decisions as to whether it was a revelation or not, yes. They could have made that independent decision, sure.

Q. Let me refer you to Dr. Dierksheid's memo. The second paragraph states:

> The planning report from the Dialysis Use Committee has been completed and sent to you for your information. This document is for internal planning purposes only. Because its findings are inconclusive, the Committee asks that the report not be distributed outside the Center.

Could this request to the committee perhaps explain why this report was not shared with the NCHSR during its recent health technology assessment or for that matter with the Senate Committee on Aging prior to its March 6 hearing?

A. I doubt it. Absolutely not.

Q. Do you think this report should have been shared with the Senate Committee on Aging prior to the March 6 hearing?

A. I think it is, as it says, an inconclusive report. The fact that it wasn't shared suggests—may bring up some elements of paranoia and it may have been better to let them have it. So from that standpoint, it would have been better to let you draw the conclusion that it was inconclusive. The fact that we didn't share it with you, you can draw the conclusion that we are hiding something from you, which is a wrong conclusion.

Q. When was the decision made to have Dr. John Marshall, Director of NCHSR testify on behalf of PHS instead of Commissioner Young?

A. I don't know that. I assume that decision was made by the Acting Assistant Secretary for Health because the elements of the Department that were involved, both CDC, NIH, FDA—because those elements were involved in it, was probably—probably supposed that someone in a position like Dr. Marshall working out of the Assistant Secretary for Health Service was in a better position to cover the overall Public Health Service. But I do not know the answer. That is my speculation.

Q. Nonetheless, were you aware at the time of the February 21 letter of invitation to Commissioner Young for his testimony?

A. Yes; I think so. Yes; I am sure I was aware of it.

Q. Do you know why Dr. Marshall was chosen as a witness? Did anyone share the reasoning for that with you?

A. No. I thought I just gave you my speculation as to why.

Q. I would prefer not to have speculation.

A. The answer is I do not know why he was chosen.

Q. Prior to his testimony on March 6 did you or to your knowledge did anyone else within your Center or within FDA assist Dr. Marshall and his staff in the drafting of his testimony?

A. We have had an opportunity to review it. I don't think we were involved in the drafting of it. I didn't. I certainly was not involved and I don't know that anybody was involved. They may have called up and asked for a sentence or two but I am not aware of that.

Q. Did yo have any occasion to review the testimony before it was delivered?

A. Sure.

Q. You did?

A. Yes.

Q. Did you take issue or did you feel that the testimony should have revision and if so, did you revise it?

A. We may have. I don't remember. We may have provided suggestions. You probably have the earlier drafts and know more about it than I do. So what are you driving at? I am not aware of anything peculiar in the evolution of that testimony. I am not aware of any disagreements or objections or problems in the evolution of that testimony.

Q. Now you stated we may have done some revisions. Who would we include?

A. Jim Benson—Bob Eccleston who has been involved with that kind of liaison involved with congressional materials going on. It is most likely if someone in the Department called up they would have talked with Bob directly.

Q. He would have been the one to liaison with NCHSR?

A. Yes. The three of us would have been involved. If anybody else on the staff was formally asked, we would have wanted to have it run through either Bob, Jim or me.

Q. Is it not the case that because of the very short notice to NCHSR, that Dr. Marshall had been chosen as the witness? Have I said anything you disagree with so far? It was on short notice, wasn't it? Wasn't it a matter of days? You got the invitation for the Commissioner on February 21, which is, what, 10 or 12 days before the hearing. It was fairly short notice, wasn't it?

A. Is that short as far as congressional notices go? I don't know. Is 10 days short? Ten days is 10 days.

Q. What I am getting at is when the decision was made for Commissioner Young not to testify and for Dr. Marshall to be the witness, was that not just a few days prior to the hearing itself?

A. I think it was.

Q. As a result of that, is it not the case that the NCHSR, Dr. Marshall and his staff, relied fairly heavily on FDA for information and material in order to put together the testimony?

A. I assume that they relied on whatever we had provided them in the past and that we played a key role in it as well as NIH and CDC.

Q. As a matter of fact, a few days prior to this hearing, I understand someone on your staff passed on a rather voluminous briefing book that originally had been put together for the Commissioner, if he had been the witness. Do you recall that?

A. Passed on to whom?

Q. To Dr. Marshall?

A. I would imagine Bob Eccleston in the preparation of the hearing book, which is normal procedure for any person testifying on the Hill—Bob normally puts a book together, a series of books, and since Marshall was testifying, I think he did provide a copy to Marshall as he did to me.

Q. Of the entire briefing book?

A. I assume it is the entire briefing book. I don't know.

Q. Did you receive a copy?

A. I had a notebook, yes.

Q. How thick was it? Was it a couple of inches, 3 inches, 4 inches?

A. It was voluminous. It was a three ring binder, probably a couple of inches. Now——

Q. Did that—I am sorry. Go ahead.

A. I was going to clarify the aspect of a briefing book. Normally when I have testified before folks here, Bob puts material in the form of a briefing book, which he feels in his best understanding of the problem and searching with the staff who are involved with this, contains the necessary background material and profiles of the folks up here around the table who would ask the questions and all of that other sort of stuff. Usually when I get the book I deep six large portions of that because if does not do any good to come in to a hearing with all that stuff.

So I go through and—for instance, it is very little value to know the profile of Senator Heinz or Senator Glenn while I am at the hearing. After I have read them I throw it out, with due respect to the gentlemen, and any other background material that I think is not going to be useful in making the points.

A briefing book is not a briefing book for me. It is an evolving three ring notebook that allows me to store stuff that I may need in addition to what Bob may have provided me. There is no such thing as a briefing book, volume such and such, that one could hold up and say this is it. What Bob provided to Marshall is probably very similar.

Q. Do you think it is possible that this briefing book could have contained a copy of the Dialysis Use Committee report of October 23, 1984?

A. It probably did.

Q. Your copy?

A. Probably. I don't remember.

Q. Do you know if——

A. Bob is so thorough, I would imagine it would be in there.

Q. Do you know if a copy of the briefing book that went to NCRSR had a copy of this?

A. No. I don't know. I wouldn't be surprised but I don't know.

Q. Prior to the March 6 hearing, did anyone, including yourself, inform Dr. Marshall that FDA was opposed to clinical trails of reuse as well as to regulating and inspecting dialysis clinics because these activities would require additional and substantial resources that were not at that time and still are not available?

A. It is two questions. You are asking one as it relates to clinical trials and I think you are asking the GMP question. May I separate those?

Q. Please do.

A. FDA does not do clinical trials or require them other than for products that come into the inventory or introduced into commerce so we don't have a way that we can mandate clinical trials. Therefore, to say that we are opposed—to try to explain—I don't understand the context of being opposed to clinical studies. We may have said it and you may have pulled back out of context of what we said before.

Q. Feel free, please, to correct the context.

A. I don't know why we would have said it because we don't do clinical trials other than for those products which come under premarket approved. This is not a so call PMA product. Therefore, I don't think it is an appropriate—it sounds like a strange response for FDA to make.

Q. Would you go on to the second one?

A. The second question is were we not opposed to good manufacturing practices because of the economics or the cost of what it would cost the agency. I am opposed to, I can't recall all of the reasons that may have been stated before, to doing good manufacturing practice because it is dumb. I don't think it makes sense to impose a requirement on kidney dialysis centers through the incredibly burdensome regulatory process of the Food and Drug Administration regulating the practice of medicine, in fact, the expensive process, because it would require more staff, and also I am opposed to it because the existing good manufacturing practice regulations are directed to manufacturers and the applicability of them to, if one were to mandate these, for dialysis centers—they would have to be so entirely rewritten that they are not applicable, other than GMP's are applicable.

The utility of the existing GMP regulation as published in the Federal Register to a clinical environment would be zero. You would have to start over and redo them. One could do that but it would not be easy to take the existing GMP intended for manufacturers, to plug that into a clinical environment and expect that to work.

But most importantly you must understand that the problems of kidney dialysis are broader than the problems of reuse, and the issue is dialysis across the board, not just reuse and we would be concerned that what needs to be done is approaches, call them good practices approach, the AAMI guidelines or what have you, for dialysis across the board, if those were to be instituted, then we think they would be accomplished what one is trying to do through reuse, through GMPs through reuse, as well as accomplish the applicability for single use centers.

Q. Do you recall Dr. Marshall having cited during his testimony March 6, the 1981 report on Multiple Use of Hemodialyzers as one of the studies supporting the contention that reuse of disposable dialyzers is safe and efficacious? Do you recall that?

A. I was there but I don't recall that.

Q. Page 56 and we will show it to you now.

A. Concluded that the care with which a reprocessing procedure was applied was critical for satisfactory clinical results.

[Pause.]

A. What was the question?

Q. Were you aware of the fact that he cited this report in order to substantiate the claim that was made in testimony that reuse of disposable dialyzers can be safe and efficacious?

A. I remember both observations, whether he used that to make his point or not.

Q. Didn't FDA at that time, and don't you still, rely upon this report in part, in your belief that reuse and reprocessing of these dialyzers can be safe and efficacious?

A. Yes. If you are referring to the Deane report——

Q. Yes, that is the Deane report, as it is known.

A. Yes. Do you want to illustrate why the Deane report is flawed so we can get on with that?

Q. Are you now and were you, on March 6, aware that this report was produced by the National Nephrology Foundation under contract to NIH?

A. Yes.

Q. Are you now and were you on March 6 aware that much if not most of the information and data upon which Dr. Deane, the principal author of this report, Norman Deane, allegedly relied to write the report originated from research and study performed by a subcontractor of the National Nephrology Foundation, Arthur D. Little? Were you aware of that?

A. I was aware of that.

Q. When did you become aware of that?

A. I don't know.

Q. Was it prior to the March 6 hearing?

A. I think I knew that Arthur D. Little was a subcontractor prior to the hearing.

Q. Do you recall who told you that?

A. Probably Larry Kobren, I don't know.

Q. Have you or to your knowledge anyone else within your Center read the Arthur D. Little report entitled The In-Vitro Evaluation of Certain Issues Related to the Multiple Use of Hemodialyzers, and dated February 1? Have you read that?

A. I know about it. I don't know who in the Center may have read it. I don't know how extensively they reviewed it. I know it has been talked about.

Q. Has anyone given you an overview or a summary capsule?

A. I think there was some concern as to whether—how objective those comments were and whether they necessarily changed the original Deane report conclusions.

Q. Are you now and were you on March 6 aware that ADL, the Arthur D. Little firm, was not permitted to review the Multiple Use of Hemodialyzers prior to publication by NIH, were you aware of it then and are you aware of it now?

A. It seemed to me I recall that came up but I don't remember specifically.

Q. Are you now and were you on March 6 aware that ADL charged in a letter dated October 9, 1981 to Dr. Norman Deane that the findings of ADL had been misrepresented and malinterpreted in the Multiple Use of Hemodialyzers report? Were you aware of that? If so, when?

A. I know that subject came up and was discussed by the staff that was involved with the over use issue.

Q. Have you read this letter?

A. I don't know. I must have but I don't remember.

Q. You don't recall when?

A. No.

Q. We will provide you with a copy of the letter so perhaps you can refresh your memory.

Are you now and were you on March 6 aware that Dr. Deane as well as the NNF, National Nephrology Foundation, and NIH, failed to address the complaints and charges of ADL contained in the October 9, 1981 letter? Are you aware of that and you aware on March 6?

A. I don't know that I was aware of that on March 6. Part of our discussions since then, this had come up.

Q. Are you aware that NCHSR staff had met with Dr. Deane following the March 6 hearing to discuss the controversy raised by the ADL letter, are you aware of that?

A. No.

Q. Are you aware at that meeting Dr. Deane was unable to refute the charges in the ADL's October 9, 1981 letter? Are you aware of that?

A. No.

Q. Let me now share with you——

A. That does not mean that the Center staff were not involved with this. The mere fact that I may not know about it does not mean that this was not made aware to the people on the staff.

Q. In light of the fact that you appeared along with Dr. Marshall at the March 6 hearing, if your staff did know about the controversy in the October 9 letter prior to that hearing, should they not have informed you of this?

A. They may have. They may have put it in the context that they disagreed with it and that there were other findings that would suggest that this was not particularly outstanding.

Q. Do you get that impression from reading through the passage in Dr. Marshall's testimony about this particular report that he cited—do you get the impression—does he qualify it in any way? Does he say we are offering this particular report but at the same time there has been a lot of controversy about it—as a matter of fact, the primary subcontractor had some very serious charges about this report? Does he state that anywhere in his testimony?

A. No, I did't see that.

Q. The fact that this qualifying comment to whatever degree he might have wished to make—doesn't that indicate to you that Dr. Marshall also was unaware of the background regarding this report and its controversy?

A. I don't know whether—whether it indicates that or not.

Q. Don't you feel that if Dr. Marshall had knowm, he surely would not have made the statement he did in the testimony without appropriate qualification as to the merits or the questions regarding this study?

A. I don't know that that is necessarily correct. I think certainly we all—he must know about it now. He made the same statements in the report to Dr. Windom that reuse and use is no different if done properly and so forth. I am not sure that this would necessarily have changed the testimony. I don't think——

Q. Did you know—had you known prior to March 6 about this letter and about the contents of the letter and about the fact that the National Nephrology Foundation did not respond nor did the NIH, nor did anyone else connected with this report respond to the

ADL complaints and concern, would you have approved the testimony and would you have gone along with the testimony that was presented by Dr. Marshall?

A. Well, I think the answer is that we still fell that use and reuse—reuse is no different than single use if done properly.

Q. That is not my question.

A. Therefore, I don't think there is any thing in this report that would change our position.

Q. My question is simply this: When this report was held out in prepared testimony without qualification as being supportive of the safety of reuse, if you had known about the controversy and about the complaints and so on of the subcontractor, would you, at the March 6 hearing, gone along with the testimony that was delivered? That is my question.

A. I would go along with it.

Q. On this particular study?

A. I think perhaps it would have been smarter to include some caveats to put it in context but it doesn't change the conclusion of the testimony or the conclusions of the Department.

Q. What caveats——

A. You just stated them yourself.

Q. What caveats would you as a witness at this hearing have placed on this particular reference?

A. I might have said there are some concerns reflected by the subcontractor which are not entirely supported by the scientific staff. This needs to be looked at. However, there is enough evidence to suggest that use and reuse—et cetera, et cetera.

Q. Let me now share with you the briefing paper that was prepared for Commissioner Young prior to the March 6 hearing. Had you seen this paper prior to your appearance here today?

A. Yes, I think so.

Q. Let's turn to page 7 of that briefing paper which I am assuming was passed on to Dr. Marshall, was it not, after the decision was made to have him testify? Was this not a part of the briefing book?

A. I don't know whether it was or not.

Q. Down toward the middle of the page where it states that FDA took action——

A. What page?

Q. Page 7. Down toward the middle of the page where it states FDA took action to help assure adequate reprocessing——

A. These are separate issues but both are outside the scope of——

Q. FDA took action to——

A. Freedom of choice——

Q. Are you on page 7?

A. What about free choice and informed consent? I am sorry. It says page 7.

Q. I am sorry. I could have the pages confused too. I had the wrong page number. We are on page 6, if the record will correct that. Page 6. We are looking at this particular bullet, FDA took action to help assure adequate reprocessing. All right?

A. Yes.

Q. Among these actions cited is AAMI guidelines on reprocessing 1983 to 1985. AAMI standing for the Association for the Advancement of Medical Instrumentation. Is this a reference, Mr. Villforth, to the AAMI recommended process for reprocessing?

A. Yes.

Q. Are you now and were you on March 6 aware that in addition to reprocessing and reusing dialyzer filters, many dialysis clinics also reuse blood lines, transducer filters, and dialyzers caps?

A. Yes.

Q. Were you aware of that on March 6?

A. Probably not.

Q. Probably not?

A. Yes.

Q. Why would you think not?

A. I think this is something that has come up more recently as an issue of the reuse. Certainly at the hearing you were—your graphic display—the Senator's graphic display of blood lines, caps and all of the other lines in addition to the dialyzer, very visibly presented the whole issue which was a good way of showing that the whole issue goes beyond the dialyzer into the blood lines and caps and so on. I think the issue of those items is a fairly—is more of a recent awareness on my part. The staff may have been aware of it. The fact that these are not addressed by the AAMI standard was——

Q. That was my next question. Are you now and were you on March 6 aware that the AAMI recommended practice only attempts to address reprocessing of dialyzers and not blood lines, transducer filters and dialyzer caps—were you aware of that on March 6?

A. No.

Q. You did become aware of it on March 6 though, did you not, when you saw the display?

A. Yes. I don't know whether at that time bells and whistles went off and said, I don't believe the AAMI standards address that.

Q. But you don't believe that prior to sitting at the witness table on March 6 that you had known about the other devices used?

A. That there was an issue involved with the other devices. The attention had been focused in may mind very exclusively to the capsules per se.

Q. The dialyzers?

A. Yes.

Q. Can you explain why, page 6 of the briefing paper for the Commissioner, which we understand was passed on to Dr. Marshall, did not state that these guidelines are limited in scope and contain no recommendations for the reprocessing and reuse of these other dialyzer disposables?

A. No; other than this briefing document which was an attempt to capture for the Commissioner in a relatively short period of time was not able to cover all aspects of everything that related to the issue. One has to cut it off somewhere. I think that is the reason why we didn't go into—the authors of all of this didn't go into all of the specific points.

Q. Let's move to July 8, 1986. Did you attend a meeting on that date with Dr. Robert Windom, Assistant Secretary of Health and a number of other PHS personnel?

A. No; I don't think so. That is the meeting—no; that is the first time that Dr. Windom was briefed on that subject?

Q. Correct.

A. By Dr. Marshall?

Q. Yes.

A. No, I was not there.

Q. Was anyone there in you stead?

A. You know who was there.

Q. Who do you recall was there?

A. Mr. Benson, Mr. Kobren, and Mr Eccleston were there.

Q. Now Mr. Benson did attend the meeting. What specifically did he relate to you regarding the discussion at that meeting afterward?

A. That Dr. Marshall was 30 minutes late. That Dr. Enrique Carter came in 40 minutes later. That Dr. Windom as the new person on board probably should not have been treated by having staff come in late.

Q. What did you learn from Mr. Eccleston about this meeting and the discussion?

A. Mr. Eccleston had the responsibility of briefing Dr. Windom in the absence of Dr. Marshall. Dr. Marshall later acknowledged that the meeting was incorrectly recorded. He was 30 minutes late and so since they were sitting around the table waiting for Dr. Marshall, since it was his meeting, he called it, and Dr. Windom wanted to get on with it, Mr. Benson offered Bob Eccleston to make the presentation. Mr. Eccleston had a chance to brief Dr. Windom of kidney dialysis.

Q. Did Mr. Kobren relate to you anything regarding the discussion following the meeting on July 8?

A. I don't recall.

Q. You don't recall discussing the meeting with him at all?

A. No.

Q. Did Mr. Benson inform you of the memo that Dr. Marshall had presented to Dr. Windom at that meeting?

A. I understand there was a memo handed out to Dr. Marshall, yes, that was later collected.

Q. Did he state what the memo was?

A. Mr. Benson, nor did Mr. Eccleston, and I presume neither did Mr. Kobren, have an opportunity to read the memo so they didn't know quite what was in it.

Q. You are saying they told you they didn't read the memo?

A. That is my understanding, yes.

Q. Did the memo have a cover to it?

A. I wasn't there.

Q. Wasn't the first page exposed?

A. I wasn't there, I don't know. I imagine it had a cover to it—are you saying wasn't it possible to sneak a few words in while it was sitting in front of them.

Q. I am having difficulty understanding how a memo could be distributed to a whole room of people, as I understand it, and not be read.

A. It is not unreasonable. You distributed to me a bunch of documents. I have only taken a few sentences out of context. The mere fact that they are sitting under my nose doesn't mean I have read them. And the mere fact that somebody at a meeting like that would distribute a document while conversation is going on doesn't necessarily mean they read it. I am under the impression they did not read that. They may have looked at it but they did not sincerely know what was in the memo.

Q. Have you read the memo since?

A. Yes.

Q. When did you first read the memo?

A. I think when you gave it to us or somehow you provided it to us.

Q. It is in the record. If we provided you with a copy, then it is in the record. In the green book?

Mr. SCARLETT. Can you explain that?

Mr. MICHIE. That is the hearing record.

The WITNESS. That is the March hearing.

Mr. MICHIE. That July memo is in that record, in the appendix.

The WITNESS. I didn't realize that.

By Mr. MICHIE.

Q. Did Mr. Benson relate to you what occurred at the meeting regarding the disposition of the memo? Did he tell you what happened with that memo?

A. He said it was collected and I guess returned to John Marshall.

Q. Did he say why it was collected and returned?

A. Well, I think there was some concern expressed that perhaps it was premature. I don't know the details. You have from Benson who was there and was a firsthand witness. It wouldn't do me much good to speculate. You had him yesterday.

Q. Did either Mr. Benson, Mr. Eccleston, or Mr. Kobren following that meeting inform you of the following: That Dr. Marshall had been admonished by Mr. Grossman for having written the memo in the first place, and that Mr. Marshall was instructed by Mr. Grossman to dispose of the memo? Did either of the three people I just named relate that to you?

A. I don't know whether it was admonished or concern expressed. I understand there was some concern expressed and that the memo was to be rushed but what the nature of the concern was, I can't explain. Certainly sorry I missed that meeting though.

Q. Let us share with you a copy of that memo at this time?

Mr. SCARLETT. Can I suggest when we reach a natural breaking point we take a break?

Mr. MICHIE. That is a good suggestion. We will just finish with this and then take a break.

By Mr. MICHIE.

Q. Is that satisfactory?

A. Sure.

Q. Why don't you take a couple of minutes to scan this, to refresh your memory?

Why don't we take the break now? Let's go into recess for the next 5 or 10 minutes.

[Discussion off the record.]

By Mr. MICHIE.

Q. Have you had a chance to review that memo?

A. Yes.

Q. I would like to refer you to the first paragraph on page 1 wherein it is stated:

> As events have unfolded, it is clear that the March 6 testimony was not based on all of the germane facts and that we may need to take a position counter to that which we argued on March 6. We need to ascertain a PHS position and inform HCFA of that position so as to minimize embarrassment for the Department.

Do you know what Dr. Marshall was referring to regarding events that unfolded?

A. I think he was concerned about some of the aspects of the testimony, whether it was documents that he felt he didn't get the process of—in terms of the testimony, in terms of the testimony——

Q. And the documents as well that Senator Heinz was providing?

A. I think he was saying, oh, gee, there are some things that have happened, whether it is the CDC's, MMWR, whether it was the guidelines—whether it was the fact that the CDC standards for formaldehye may not have been standards, whether it was the NIH registry or some of the FDA information that he didn't have available, if they had been available he might have wanted to change his testimony. I think that is what he was saying.

Q. And was he not referring in that same document to memorandums and other records that Senator Heinz had obtained in his investigation of these issues and had supplied to the NCHSR, many of these documents dating back months and even years ago, that the NCHSR, at the time of the hearing on March 6, was unaware of and had not been provided by the Department? Do you think he might have been referring to that as well?

A. I think that is what he was referring to.

Q. Do you think he also might have been referring to the report, "Reuse of Hemodialyzers" that was authorized principally by Dr. Deane? Do you think he might have also been talking about that, that he wasn't aware of the controversy surrounding this report?

A. He might have but I doubt it. I should point out in subsequent discussions with Dr. Marshall, it is my understanding that, having reviewed most of the material since then, that he in fact has not—does not feel that he would need to change his testimony, that he did not have the opportunity to review these documents at the time of this July 8 memorandum, and in the absence——

Q. Do you think these documents should have been provided to him?

A. Only to eliminate this kind of memorandum but the presence of those documents would not change this testimony. He has been around and he understands the difference between CDC guidelines and CDC standards and I am under the impression, at least when we met a few weeks ago with the principals of the agency, that he is saying there is not anything new that would allow me to change the testimony. At the time he was saying, based on the material—I suspect that is the material you dropped off in a brown paper bag one night on a weekend, when he read through that he saw that that material had been provided before. With the overwhelming amount of that material——

Q. I think you may be a bit confused. What I may have picked up on Dr. Marshall's front porch were things he provided to me. With regards to the several hundred pages of documents which he refers to in the memo, these were provided to him in the comments transmitted by letter signed by Senator Heinz on June 10 in response to the Federal Register notice. Do you recall that?

A. Yes; that is right. Thank you for clarifying that.

Q. If you turn now to page 3 of the July 8 memo, to the first two sentences in the next to last paragraph, it reads as follows:

> After the hearing Dr. Macdonald directed me to carry out an assessment of dialyzer reuse. In the course of carrying out that assessment it has become evident that communications within the Public Health Service is less than adequate.

Now, what, during the course of carrying out the assessment, would have made it evident, in your opinion, to Dr. Marshall, or to your knowledge, that communications within the Public Health Service were less than adequate? Can you think of anything?

A. No. The process with which Dr. Marshall undertook this technology assessment as directed by Dr. Macdonald was by reviewing documents. There were no formal meetings in which there was an opportunity—as I understand it, an opportunity to discuss this. I think we suggested that was an approach that might be useful to get all this material and have full participation but it was decided by Dr. Marshall that he would use the same approach that he used for other technology assessments and that is rely on the literature.

Q. Could it have been the failure of FDA to keep NCHSR informed in a timely manner on the rash of infection outbreaks that occurred in April of this year—could that have been part of his concern?

A. I don't think there was any attempt to keep him uninformed. I think we tried to keep him informed of those things that were pertinent. There were infections. There were things—not reuse, problems with the sterile—we think perhaps unrelated to the issue at hand, but I think we kept him pretty well informed.

Q. Could it have been the FDA's failure to provide NCHSR in a timely matter reams of documents, as well as to FDA's "Establishment Inspection and Medical Device Reports" pertaining to death, serious injury, malfunction, extremely poor reprocessing procedures in dialysis clinics and numerious deficiencies in manufacturing practices of firms that market dialysis and reprocessing devices—could this have been what Dr. Marshall was complaining about?

A. I doubt it.

Q. You doubt it?

A. Yes.

Q. Are you certain?

A. No. You asked me for my opinion and I said I doubt it. I don't think that that material, that is, the indications of the compliance or noncompliance of manufacturers' recalls was necessarily pertinent to the issue he had no technology assessment. It would be—it might be nice to know that information but I don't think it was pertinent to the outcome of his recommendations.

Q. Is it not true that most of this material was not provided to NCHSR until after that agency had completed its assessment and had submitted its report to Dr. Windom on August 6? Wasn't that the case?

A. You have the facts. I don't recall. If that is the case—in terms of EIMDR's and so forth, I don't know when that material was provided. EIMDR reports and DEN reports—hardly any of these things were related to the issue at hand.

Q. Have you read all of this material?

A. Not all of it, no, sir.

Q. So you are surmising at this point or is it your conclusion——

A. This is a surmise, and based on discussions with the staff.

Q. Are you aware that on or about August 8 Robert Ecceleston of your staff telephoned the NCHSR staff to inform them that your Center would begin to provide NCHSR everything that your Center had already provided or was in the process of providing to the Senate Committee on Aging? Are you aware of that?

A. Yes.

Q. Are you aware that even prior to this August 8 telephone call, that NCHSR staff had been requesting from FDA whatever materials they knew existed during the course of the assessment?

A. That they had requested from——

Q. That they had made requests to FDA during the course of the assessment?

A. I think we honored all of those requests. I think we handled them expeditiously. The fact that there might have been materials that you had requested or the Senator requested that covered the whole blooming area—because in an attempt to be cooperative I think we provided you more than was necessary—the fact that we provided you more than I in my judgment would have felt was necessary within the scope of what you were looking at. That same material I wouldn't have necessarily thought would have been pertinent to Dr. Marshall's—the thrust of his report.

In an attempt to make sure everyone was communicating, because the charges were made by the Department to FDA that we were not communicating——

Q. Who made those charges?

A. I suspect in your attempt, in going around to visit people like Dr. Marshall, you pointed out that we had not been cooperating, as you pointed out had I read CDC. You have been most effective in going from agency to agency telling one agency what the other agency did or did not have. You have been most effective in sowing a seed of distrust within the Department and, therefore, with the level of apprehension that has been raised and the innuendoes of lack of cooperation, it is only natural that one should dump the file drawers and make everything available to everybody to stop the contention that we are hiding up. I think that was the context of what Mr. Eccleston was saying.

Q. I would like to share with you a copy of a memo dated April 9. It is addressed to the FDA's Associate Commissioner for Health Affairs from NCHSR's Office of Technology Assessment in which they requested any and all information regarding disalysis reuse. Have you ever seen this memo before?

A. No, but I heard about it.

Q. Do you want to take a minute to look at it, please, so you can appreciate what was asked for?

A. [Pause.]

Q. How many items were listed there?

A. Seven.

Q. Would you not agree, Mr. Villforth, that this was a rather broad request for information regarding safety and efficacy, reuse and reprocessing?

A. These requests come in all the time.

Q. Do you not agree that this covers the waterfront, so to speak?

A. Looks like it.

Q. Let me share with you a May 28 memo, May 28, 1986, memo, NCHSR's Office of Technology Assessment from FDA's Office of Health Affairs. This memo was in response to the memo we just shared with you, the April 9 request for information.

This memo of may 28 in response tells NCHSR the following: "All information concerning the issue of reuse of dialyzers, blood lines, transducer filters and dialyzer caps is already available to OHTA," meaning the Office of Health Technology Assessment within the NCHSR, "as part of the package prepared for the Senator Heinz hearing. The Office of Device Evaluation has no additional information."

Now is not the Office of Device Evaluation in your Center?

A. Yes, that is correct.

Q. Now tell me, Mr. Villforth——

A. Where are you reading from?

Q. The May 28 memo. It states, "the Office of Device Evaluation has no additional information."

Now bearing in mind this was May 28, was this a true statement at that time?

A. I would think so.

Q. You would think so?

A. Sure.

Q. That there was no new information about the infection outbreaks, for example, that began in early April?

A. That was pertinent to the assessment——

Q. Pertinent to the safety and efficacy of reuse?

A. Not in term of reuse, no.

Q. Despite the fact the April 9 request, as you just agreed, was very broad, covered the waterfront, you are saying that you feel this was a true statement, that everything that had been given to OHTA prior to March 6 was everything that there was reposited in your files. Is that correct?

A. No, not everything. Everything we would have thought was pretinent to the thrust of the assessment report that he was working on. Yes, there were recalls; yes; there were problems with some of the dialysis solutions. Yes, there were use problems not—most of these were use problems and not what I would have thought would have been under the scope of this kind of technology assessment.

In retrospect, because of the suspicions, it probably would have been smarter for us to provide it so we don't have any suggestions that we were holding anything back but I think at the time—if I had to do it again I would do the same thing.

Q. If you had to it over you would still have not provided them with that all that material pertianing to EIMD's and all of the rest of it?

A. Unless it was pertinent to the question of reuse. The mere fact that we have things in the EIMDR that is related to dialysis doesn't necessarily mean it was pertinent. We can't assume when the word dialysis pops out in MDR it is going to be related to the thrust of the technology assessment.

Q. You seem to be making a difference between a reuse and use and I don't quite understand your point. Flush that out for me a little bit. Why are you making this difference between use and reuse? What is the difference, in your mind?

A. Well, a lot of the concern has been directed by the Senator certainly to the question of reuse and the problems that are associated with the problem of reuse because the presumption is they are reused too many times and improperly and therefore there are deaths and illnesses associated with the process of reuse.

Q. Let's take—by use, what do you mean by use?

A. The use may be a problem with deaths associated with inadequate filtration of the incoming water supply in which chloramines get into the dialyzers and it gets into the patient.

Q. What is that, by contaminated water?

A. Yes.

Q. That is used in reprocessing?

A. Whether it is usual use or not it doesn't matter.

Q. Doesn 't that impact on reuse?

A. If that is in fact a problem that is related to reuse. It is also a problem related to use. There is nothing unique about the reuse that makes that a particular problem. In other words——

Q. What are you saying is that these problems can impact both reuse and use?

A. Many of these problems are related to use and reuse and when you pull reuse out of context there may not be something that is unique to the aspect of reuse that we should focus attention on. The problems as we have been trying to suggest all along are basically problems of use, temperature controls or water processing problems, which is—reuse or use, immaterial.

Q. Would it surprise you to know, Mr. Villforth, that after receiving these reams of materials, doucmentation, and so on, most of it not until August 11, from your Center, that the staff at NCHSR is indeed interested in much of that material and does indeed feel that the material is germane or would have been germane to the assessment? Would that surprise you?

A. Yes.

Q. No one, to your knowledge, or as best you can recall, has ever conveyed that information to you?

A. No. As I said, about 2 weeks ago we had a meeting where Dr. Marshall was there, his concern with NIH, his concern with FDA. I am under the impression—I thought I heard him say, I understand now and probably this memo is not really appropriate anymore.

Q. To your knowledge have Dr. Marshall and Commissioner Young communicated with each other in writing on a confidential basis concerning the FDA's failure to share with NCHSR in a timely manner documentation, data and information reposited in FDA files and germane, in the opinion of NCHSR, to its assessment? Are you aware of their communications of that kind?

A. I don't know whether germane is appropriate. The question is there may have been documents that were not provided to NCH—whatever, by FDA, certainly the initial documents were not originally provided to Marshall and he provided a list to Dr. Young of pages of material of which I don't known how many documents that Marshall said he didn't have.

Q. Was this stamped confidential?

A. Was Marshall's note stamped confidential? I believe it was.

Q. Do you have a copy of it?

A. I have seen a copy. I don't know whether I have a copy. I probably do. I don't keep copies.

Q Will you share that with us?

Mr. Scarlett. We will take the request under consideration.

By Mr. Michie.

Q. Have there been any other such communications labled either confidential or for administrative use only pertaining to reuse of these devices?

A. Not that I am aware of.

Q. Have you generated or received any such communications from anyone?

A. No.

Q. Regarding this issue?

Q. No.

Q. When did you and your Center first learn of the infection outbreaks in the several States that came to light starting in early April of this year?

A. I don't know. Soon after they happened.

Q. Would it have been days or weeks? Would you have known by May?

A. I think Jim Benson sent a memorandum up to the Commissioner to the effect of some of the problems that were identified—I don't remember the date of that memorandum—it was about that time.

Q. But by word of mouth when, as best you can recall, did you learn or when were you told about these infection outbreaks, the first of which occurred in early April, in Englewood, CA, do you recall?

A. Yes. I don't remember the date.

Q. Do you think it would have been prior to June?

A. I think so, yes.

Q. You think so?

A. Yes.

Q. Are you fairly certain?

A. No.

Q. But you think it probably was prior to the month of June?

A. Probably?

Q. Do you recall how you came to learn—from whom did you come to learn about these outbreaks?

A. I suspect Bob Eccleston briefed me on the information that came in to the system.

Q. When did you and your Center begin to inform NCHSR of the infection outbreaks?

A. I don't know.

Q. Do you know whether or not NCHSR was formed of these outbreaks in writing?

A. I don't know.

Q. According to the records from your Center FDA and CDC conducted the first joint investigation of these outbreaks in Englewood, CA on May 10. There was some delay after the reporting. CDC and FDA were involved. Were you aware of that?

A. Yes.

Q. This was the first of these outbreaks involving RenNew-D.

We would like to share with you now a copy of a memo dated June 25, 1986, written by your deputy.

A. To the Commissioner.

Q. To Dr. Marshall in which Mr. Benson informs him of the RenNew-D recall and the infection associated with the use of the chemical. Was this the first notification to Dr. Marshall concerning these outbreaks?

A. I don't know. There may have been a telephone call. I don't know.

Q. Getting back to the March 6 hearing, Senator Heinz having questioned about the Reuse Committee's February 24, 1986 "Working Paper: Policy Considerations for the Reprocessing of Devices"—can you tell us what is the current status of that paper?

A. It is still that, a working paper.

Q. Is it still in draft?

A. I guess as a result of the work of your fine committee it is now in—published in its entirety of the last issue of the dialysis magazine. What is the name of that? I just saw that this morning.

Q. Is that right?

A. Somehow it got to them. I can't imagine how else it would have gotten to them.

Q. As a matter of fact, Mr. Villforth, that February 24, 1986 version was an exhibit in Senator Heinz's petition to the FDA to impose GMP's, and as you know, whenever such a petition is filed with the agency, it becomes a matter of public record.

Do we have that?

Let's take a 3-minute recess and I am going to get that paper for you.

A. What is the name of that magazine?

Q. I have no idea.

[Pause.]

Q. Here is the original. If you want a copy, we will have to make one.

I would like you to look toward the bottom of the first paragraph of the first page. "The Committee believes that FDA has the authority under the existing law to regulate processing of devices for reuse whether it is carried out by the original manufacturers, health professionals, or others."

Do you know what the basis for the committee's belief is, Mr. Villforth?

A. No.

Q. Do you disown it?

A. Well, you are asking a committee of scientists to render an opinion as to whether the law is applicable to that process. I don't think you could trust that necessarily they are familiar enough with the law to know whether in fact that is a correct statement or not. That is their opinion as to how they would see the law's interpretation.

Q. Did they not consult with your own general counsel?

A. I understand they had some discussions with a member of Mr. Scarlett's staff.

Q. Is this belief not based on those discussions?

A. I don't know that. I don't know that.

Q. Would you care to comment on that, Mr. Scarlett?

Mr. SCARLETT. No, I wouldn't. In a second I am going to invoke the privilege.

Mr. MICHIE. For the sake of clarification?

Mr. SCARLETT. No.

Mr. MICHIE. Are you invoking the privilege?

Mr. SCARLETT. I said I was about to. In response to your question, I do not wish to clarify.

The WITNESS. The issue is not a legal issue as to whether one gets involved in the question of implementing the regulatory approach at the Food and Drug Administration to reprocessing centers. Whether or not it is legal or what counsel would or would not say is a moot point.

By Mr. MICHIE.

Q. When did you become aware that Donald Macdonald, the then Acting Assistance Secretary for Health, had requested NCHSR on March 5 had to conduct an assessment of the safety, efficacy and cost effectiveness of dialyzer reuse within 60 days—when did you learn this?

A. I remember Marshall talking about that he was getting that assignment at the time of the hearing or while we were getting together in preparation for the hearing, but I don't know that I ever saw the piece of paper. I understood the assignment was being given to him.

Q. Did anyone within FDA, PHS, HCFA, or CDC at any time during the course of the assessment state to you that this assessment of dialyzer reuse was not a regular assessment and that it had to be done in a hurry? Did anyone ever give you that impression or convey that idea to you?

A. Well, it was clear that there was a need to get on with the job but I don't know what you mean that it was not a regular assessment. The fact that Enrique Carter wrote to Dr. Nightngale putting this in the normal track was an illustration that they, Carter, et al., were considering this somewhat of a normal process. I don't remember what the timetable was on that.

Q. Was it not June 10, wasn't that the original deadline?

A. I know there was an earlier expected date. I think it was June 10, yes.

Q. Did anyone within FDA, PHS, or HCFA at any time during the course of that assessment inform you that completing the assessment and a report as soon as possible was important to HCFA because that agency was preparing to publish a proposed regulation to reduce Medicare's dialysis reimbursement rates?

A. I guess I knew that they were going toward some sort of final regulation—that HCFA was working on a final regulation. I didn't know that I knew how this was necesssarily interrelated to it.

Q. Did Dr. Marshall or anyone else within NCHSR, FDA, CDC or anyone else in the PHS or from HCFA at any time during the course of the assessment make you aware that if the NCHSR assessment report concluded that there were dangers associated with reuse, HCFA might have difficulties in going through with the reduction of the reimbursement rates? Anyone ever make you aware of that?

A. No.

Q. Let's go back now in time to April 1986 and I will share with you a copy of a letter dated April 29, 1986, to Senator Heinz from Secretary Bowen which responded to Senator Heinz's letter of March 21 of this year. That March 21 letter from Senator Heinz, as you may recall, urged the Secretary to impose GMP's upon reprocessers of these disposable devices. Secretary Bowen informed Senator Heinz that the "Food, Drug and Cosmetic Act specifically exempts from device regulation practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propogate, compound or process drugs or devices solely for use in the course of their professional practice."

Was this the position of the FDA then and has it continued to be so to the present, to your knowledge?

A. I don't know if—you are talking about a legal interpretation. I believe this statement was written by counsel in the Department. Whether that is—how much consultation there was with Mr. Scarlett's office or not, I don't know. Whether that is or is not in the opinion, I don't know. The facts are, as I said before—this is not a legal issue as to whether we do do GMP's or don't do them.

Q. Why then would the Secretary cite them?

A. He didn't ask my opinion.

Q. Can you come up—can you at least give some idea for us why he might have done so if it is not a legal matter involved?

A. No, I can't surmise why the Secretary did it. We were not involved in the preparation of that statement so I don't know. It is not something we had put together for the Secretary.

Q. So in other words neither you nor anyone else in your Center assisted in drafting or reviewing that letter?

A. That is right.

Q. Are you certain of that?

A. No, I am not certain of that. I should qualify that.

Q. If there had been review or assistance from your Center, who might it have come from if it didn't come from you?

A. It could have come from Bob Eccleston or Jim Benson.

Q. Might there have also been assistance from the FDA's General Counsel Office?

A. They could have been but they are not at our Center. You asked about the Center. I can only account for the Center.

Q. I would like to share with you a one-page memo dated April 16, 1986, to the Secretary from Dr. Macdonald, then Acting Assistant Secretary for Health. The memo advises the Secretary on how FDA believes it should respond to the March 21 letter to the Secretary in which the Senator urged that the FDA GMP's be imposed.

Had you seen this prior to your appearance here today?

A. I may have written it. I don't recall.

Q. Please take a minute to look at it.

[Pause.]

A. OK.

Q. Did you or did anyone else to your knowledge in your Center assist in drafting or reviewing this memo prior to it being forwarded to the Secretary?

A. I don't know. I didn't.

Q. Please take note of the third paragraph wherein Dr. Macdonald states "FDA believes the response to the Senator should state that dialyzer reuse is exempt from FDA regulation. FDA's general counsel has concluded that a legal argument can be made either way for imposing GMP's or not."

Were you aware at that time that your own general counsel believed that a legal argument could be made for imposing GMP's and therefore it was a policy decision for the Secretary? Were you aware of that?

A. My understanding is that it was not clear.

Q. That it could go either way?

A. It could go either way, depending on interpretation.

Q. And therefore it was a policy decision?

A. What was a policy decision, as to whether we do or we don't?

Q. Yes, for the Secretary to make?

A. That the Secretary therefore could—it could have been made by me. Didn't have to go to the Secretary.

Q. But if it did, regardless of who made the decision, it was a decision that could have gone either way, it was a matter of policy, was it not?

A. That is, if the legal opportunities are either way, then the way you come down is no longer a legal decision. What else you may call it, policy or common sense—yes, it is a nonlegal decision. Is that what you are asking?

Q. It is a policy decision, is it not?

A. I guess. It is a nonlegal decision, yes.

Q. You can either go with a policy opposed and clutch the argument against imposing GMP's or you can take the argument for imposing GMP's. Isn't that policy?

A. It is a decision not based on a legal restriction. I think that is what we are saying. That policy—whenever you make a decision, I suppose that is policy—is that what you are saying?

Q. I am asking you because it would seem to me that this would be a matter of policy. If you had free choice of whether to go for or against, policy would determine which was chosen, would it not?

A. If we had free choice and that were the only decision, then whether we did or—it seems like a stupid argument. If you want me to say it is a policy decision, I will say it is a policy decision.

Q. I would like you to say only what you wish to say.

A. I want you to understand whether legally you can do this or you cannot do it, there are other overriding circumstances as to whether one should go ahead and implement the good manufacturing practices. Those discussions I discussed previously.

Q. Getting back to this memo, was it your advice or to your knowledge the advice of anyone else in your Center for the FDA to recommend that the Secretary adopt a policy in opposition to imposing GMP's on these reprocessers? Did you ever make such a recommendation?

A. I certainly wanted to make the Secretary—if I had the choice, I would want the Secretary to be aware that we should not go with GMP's.

Q. Did you do so?

A. No. I think we tried to convince the Commissioner and anyone that would listen to us.

Q. Did you succeed with the Commissioner?

A. I think the Commissioner understands clearly, yes, and we would be the person to influence Dr. Macdonald or the Secretary.

Q. Right on up to the Secretary?

A. If the Secretary wrote it I suppose someone—he signed it.

Q. I have a memo dated April 21, 1986, to the Secretary from Anna Boyd who is policy coordinator in the Department's executive secretariat. Do you know Ms. Boyd?

A. No.

Q. Have you ever discussed anything with her?

A. No.

Q. This memo also is regarding Senator Heinz' March 21 letter to the Secretary. Had you seen this memo prior to coming here today?

A. No.

Q. Did you, or to your knowledge did anyone else in your Center assist in the drafting or review of this memo prior to it being sent to the Secretary?

A. I did not and I doubt if anyone in the Center had any involvement with it.

Q. Did you or to your knowledge did anyone in your Center have occasion to discuss the contents of the memo with Ms. Boyd prior to her finalizing it?

A. No. I guess that is sort of an obvious no. If I hadn't seen it and wasn't aware of it before now I wouldn't be involved in it.

Q. Is is possible that someone in your Center was?

A. It is always possible. It is very unlikely.

Q. Let me call your attention to the fourth line from the top of the second page of the memo, which reads as follows:

> FDA strongly opposes applying GMP standards in this area and has taken the position that we should tell Senator Heinz in this letter that the GMP regulations do not apply in this order to "close the door" to further pressure from the Senator.

What is the basis for FDA's strong opposition to applying GMP, just for clarification?

A. I did it before but since it is not clear and since it is a very important point I will try to do it again. There are several reasons. One, the good manufacturing standards, GMP standards as written and published in the Federal Register were intended for manufacturers, industry. They are standards which require that a lot of attention be paid to incoming raw materials, validation of the raw materials, that proper documentation of processes be put into effect to that one can have traceability with the end product as it comes off the assembly line and gets into commerce so that if we need to go through recalls, there is a good history and documentation so that one can identify a particular batch of materials that may have failed in one way or other or it needs to be recalled.

More importantly, by the imposition of GMP's, we hope to eliminate recalls because it imposes on manufacturers, industry, the kinds of sensitivity for quality in their work, documentation, attention to details, et cetera, et cetera that are necessary to make quality products. Whereas there are tests and there are imposed on the manufacturers certain tests, the end product is to result in primarily the assembly line production of quality materials.

Now when you take that out of its context and attempt to apply those sorts of standards or procedures to a clinical environment in terms of reuse, very little of what has been written in the Federal Register would be applicable. Now it is not impossible to take the philosophy that we have a GMP approach and we could use it for dialyzers but we would have to go back to the drawing boards and restructure it and publish in the Federal Register. It is not impossible.

Q. You would have to come up with standards?

A. Entirely different standards for reuse. It is not impossible to take the framework of GMP's but it must be very clear that one could not do this initially now with the existing GMP's as written and published in the Federal Register. No. 1.

Q. Can you give us an idea at the present time, over the past 10 years, since the agency has been given authority to promulgate such standards, how many such standards have you promulgated for medical devices?

A. Well, you are asking the wrong question but I will answer your question. The GMP procedure, good manufacturing procedures, apply to every medical device.

Q. I am talking about specific standards, how many specific standards for which you have authority to promulgate have you promulgated in the past 10 years?

A. Under the medical device amendments we have not done any.

Q. Not any. Not one?

A. Well, of course, one could interpret—we do have standards for medical x-ray equipment, standards for medical lasers.

Q. But that is a different category. We are talking about medical devices, durables, that sort of thing. I want to be sure I understand you.

A. Under the procedures of the Medical Device Amendment we do not have mandatory performance standards for products. Although we have authority to do that, and we are expected to do it for those products in class two, approximately 1,100 products in class two, I believe we have not done any in class two.

Q. What class are these in?

A. These products are in class two.

Q. Class two?

A. That is correct.

Q. If you wanted to, you could promulgate standards?

A. Yes, for the manufacturers of these.

Q. What about the reprocessing?

A. No I don't think that would be appropriate.

Q. Are you suggesting that you don't have legal authority at the present time to promulgate such standards for reprocessing?

A. We probably could set standards for reprocessing. We would have to again discuss it with counsel, if we did have the authority, we probably could set standards for the reprocessing. The question of the efficacy of those standards is another point.

But to continue——

Q. Please.

A. Thank you. I wanted to make the point that the existing GMP's as stated don't apply. The GMP's would have to be rewritten. You raised the point correctly that one could take regulatory performance standards and apply these to that product. These are standards of performance and the kind of thing that would require, of course, inspection against them, we do inspect against them, which requires some commitment of resources and this was not the predominant reason but certainly is the question of the commitment of resources.

Q. And yesterday, Mr. Benson made the point in his testimony in deposition that I think the estimate was, correct me if I am wrong, Mr. Scarlett, somewhere around $750,000——

A. Three-quarters of million dollars.

Q. Do you feel that that is an inordinate amount of money to be dedicated to such a program?

A. It is not the number, and I don't remember the number of full-time equivalents pulled off other jobs, when you look at the priorities, when we have to make programmatic decisions, is this higher or lower than heart valves or higher or lower than sterility of other products and it is not there, as far as its effectiveness of those inspections, it isn't there.

Q. If you did have $750,000——

A. I wouldn't spend it on that process. I would take it and put it in higher priority.

Q. Suppose you reach the bottom of the barrel of your priority list, is that where this particular inspection would be reside?

A. If I had all of the money that was necessary and there were some prioritization scheme and I mentioned earlier we are trying to do that, numerical quantification, and this was next in line, certainly, but there are products ahead of it.

Q. Would have you——

A. We have 8 to 10,000 deaths a year in anesthesia related equipment. We don't have a lot of bodies lined up.

Q. This committee certainly appreciates that. Where would the priority be for this particular area of inspection? Would it be toward the middle, would it be toward the bottom of your priority list? Where would it be?

A. Probably be toward the bottom because you are now dealing with an inspector that woul have to spend a full day making an inspection and the effectiveness of that inspection is—he may be dealing with how many patients, 50 patients. Where the same inspector goes into the factory and that equipment may deal with thousands of patients or users or consumers which may be a much riskier product. The question is not that we didn't do something better. The question is is that the mechanism to deal with it and we are talking about then the 60 percent of the facilities where they are being reused. We wouldn't be affect—having any effect on the 40 percent that don't reuse because they wouldn't be reprocessing and they would be exempted from the FDA's regulatory approach and we said earlier the problems of reuse and the problems of use are very similar. We are dealing with the same concern about incoming water supply and temperature supply, et cetera.

Q. Getting back to Ms. Boyd's memo, did you or anyone else in your Center advise Ms. Boyd that FDA had taken the position that the Secretary should tell Senator Heinz that the GMP regulations do not apply in order to "close the door" to further pressure from the Senator?

A. If they had asked me, I would have said, would you please tell Senator Heinz that the insistence of pursuing GMP's is dumb. Please make that point to the Senator somehow, Mr. Secretary. It is not a legal issue. No one asked me.

Q. Ms. Boyd attributes this advice to the FDA. Do you have any idea at all where and from whom she got this particular advice?

A. No. I haven't the slightest idea. It may have been even secondhand since she would presumably deal with the Public Health Service counterpart.

Q. Are you aware on May 12, 1986, Senator Heinz and five other members of this committee filed a petition with the FDA seeking to have GMP's imposed on reprocessing?

A. Yes.

Q. The petition was filed over 4 months ago. Do you know whether FDA ever intends to respond to that petition?

A. I am sure they intend to respond to it but I don't know what the status is.

Q. Isn't your staff involved in this response?

A. Yes; they are involved with it but normally those sorts of things are—others are involved in the timing of that.

Q. But 4 months have gone by. Don't you have some idea as to when this response will be forthcoming?

A. No.

Q. You are aware, of course, that there is a 180-day clock running on this particular petition. Is your staff aware of that?

A. I am sure they are as we get petitions in all the time.

Q. You think it is possible they will meet that deadline of 180 days?

A. I don't know.

Q. Let me share with you a note written by you dated June 10, 1986, to the Commissioner. Down toward the bottom of page 1 this refers to a petition filed by Senator Heinz with FDA. Was that——

A. Where are you now?

Q. On page 2. That is your memo, right?

A. Yes.

Q. It states, "We continue to stand firm on the position enunciated at the hearings and reiterated in Secretary Bowen's April 21 letter to Senator Heinz."

Why did you feel it necessary, Mr. Villforth, to reassure the Commissioner that you continue to stand firm? Do you know why you did that?

A. No.

Q. No particular reason?

A. No.

Q. Was this——

A. I would assume that we—there may have been some question that this came in as a result of—when did the Senator's——

Q. The response from the Secretary was April 29, so this was sometime afterward, June 10.

A. No.

Q. Was this promise to stand firm because of the Commissioner's strong opposition to imposing GMP's on reprocessers?

A. The Commissioner certainly is not in favor of doing this.

Q. Do you get the impression that he is strongly opposed?

A. Yes; I think he is. I am too. I hope you get that impression.

Q. Do you continue to stand firm?

A. Absolutely.

Q. I have for your reference a June 11 memo to Dr. Henry Desmarais, the then Acting Deputy Administrator of HCFA from Commissioner Young. This represented the Commissioner's comments on a "background paper" that Dr. Desmarais was to forward to the Under Secretary of the Department. Is that correct?

A. Say again?

Q. This memo that you are looking at, and I don't know whether you had anything to do with it or not, but this was in response to a proposed briefing paper, background paper that Dr. Desmarais wanted to send to the Under Secretary and I suppose as a courtesy he was running his paper by FDA for their advice and counsel. Do you recall this paper?

A. Yes.

Q. Did you in fact have anything to do with drafting or reviewing this paper?

A. I suspect we did.

Q. You personally?

A. I am sure—no. I was involved with it. I am sure I saw the draft as it was going out.

Q. Who would have had, do you think—who would have had primary responsibility?

A. We probably initiated a first draft. I don't know where it would have gone. We probably had the responsibility.

Q. Who specifically?

A. Probably Bob Eccleston.

Q. The last bullet on page 2 states, "We are concerned about giving too much weight to our own tristate survey since its focus is on hemodialysis problems across the board and not solely for reuse."

For the record I want to point out that the tristate survey involved the States of Ohio, California, and Massachusetts, as well as the District of Columbia. Is that correct?

A. That is correct.

Q. Now do you know why the Commissioner was concerned about giving too much weight to the tristate survey?

A. I don't remember the Desmarais draft.

Q. The draft, of course, did cite the tristate survey?

A. I don't know why. I can't place that in context.

Q. Isn't it the case, Mr. Villforth, that you as well as other individuals on your staff did not want to a lot of emphasis placed upon this tristate study which included the District of Columbia simply because it would have continued to apply pressure on the agency to take action with regard to regulation? Is that not a fact?

A. I don't think so; no. I don't quite understand how you could draw that conclusion.

Q. I asked you a question.

A. It doesn't flow from the fact. We initiated a study to look at what was happening to the—how many different facilities were there, and get experience of dialysis use and included some reuse——

Q. Including a great deal of reuse, did it not?

A. It included some reuse. I don't know what percent.

Q. If at least 60 percent——

A. This was not a representative sample. I don't remember what the number was, what the percentage was.

Q. Let me ask you, how much weight do you personally give to the survey results in determining the known as well as the potential threats to health and well-being of dialysis patients that are subjected to reuse?

A. This is anectodal. It is a snapshot. It is not statistical. It confirms the suspicions. It started out with the Dierksheide report that there is a need to pay some attention to dialysis across the board and that was an attempt—this was an attempt to get a snapshot and I think it confirmed there are some problems with problems. Considering the nunber of patients and the number of applications, not a panic, but a need to pay a little more attention.

Q. A little more?

A. Yes; a little more attention. I think the AAMI guidelines are moving along. The Joint Commission on Accreditation has just adopted, as of last month, the whole process whereby accreditation will be denied to those hospitals that don't pay attention to some of the AAMI-like guidelines. I think the Senator has been very successful in raising the attention of the community to better use of dialysis.

Q. Regardless of how you choose to characterize this tristate study, whether you wish to call it a snapshot or whatever, is it not the case that insofar as the FDA or anyone else, knowing the situation out in the dialysis clinics, knowing as to whether or not many people are contracting infections, how many people are suffering injuries, that you really don't know simply because reporting of these incidents is not mandatory?

A. There is no question that information would be underreported because there is no mandatory reporting. We have voluntary reporting and when that gets reported back to the manufacturers it is reported back to MDR. When you put those underreporting of dialysis problems and underreporting in anesthesia and other aspects of surgery, one gets a sense that there is gross underreporting.

Q. Understood. But you made the point earlier that these dialysis patients are unusually sick people, are they not?

A. Yes.

Q. If you were to pick and choose priority wise on where you would want to have reporting, where you would want to have a good idea of what is actually happening out there instead of having the tip of the iceberg, as you probably have, wouldn't it make sense to have mandatory reporting for dialysis clinics because of the sickness of these people, because these people are so frail and because when these people do contract infections they are in more danger than most people are?

A. I don't think so. I hear what you are saying, but as far as extending the reporting of that because of frail people does not make sense. One could argue if one is interested in problems, one could look at problems of apnea monitors for infants because if you fail, you destroy the life of an individual that may have 70 more years.

Q. I wasn't suggesting that should necessarily be justification for regulation. What I was suggesting was because of the physical state of these patients, because these patients are ill and frail, regardless of what vehicle or what mechanism you might want to use, would you not want to have good reporting from the dialysis clinics to know the extent these patients may be suffering from infection? That was my point.

A. One always would like to have more data and more information, yes, of course.

Q. Do you recall that during the week of June 22 CDC was in the process of drafting an article on the infection outbreaks involving the disinfectant RenNew-D for its June 27 edition of the Morbidity and Mortality Weekly Report?

A. Yes, I am generally familiar with it.

Q. The MMWR?

A. Yes.

Q. Did you become involved in discussions with Dr. Marshall or anyone else regarding the content of that article?

A. I did not, no, but I think our staff was involved.

Q. Do you know who among your staff was involved in these discussions?

A. Well, I know Bob Eccleston had picked this up when the information—I should back off. We normally, we, FDA, normally have the opportunity to review certain of the MMWR drafts as they are getting close to final, may be days ahead of time before they are published because many of these could have an impact on products we regulate and as a courtesy we have a chance to be aware of it so there is a system set up for communication through our Office of Health Affairs and in this instance the system worked and the information was turned over to Bob Eccleston because they knew he was coordinating some of our activities and when he heard about this he recognized that this might be something that should be called to Dr. Marshall's attention and I think he made the link up between Marshall and CDC.

Q. What did he feel should be called to Dr. Marshall's attention?

A. The fact that CDC was coming up with a statement on clinical trials, was the issue, I believe.

Q. Clinical trials?

A. The recommendation that they——

Q. To have clinical trials?

A. I think so, yes.

Q. Did this concern you?

A. No.

Q. Why would Mr. Ecceleston become involved if it didn't concern you?

A. I think the point was that this had to do with kidney dialysis. We had been identified as perhaps by the Department as not being team players and it was an attempt to make sure that we weren't going to be accused of learning something and not keep Dr. Marshall informed. I think Bob was saying, he ought to know about this; I wonder if he does, and he picked up the phone.

Q. What you are telling me is that the FDA took upon itself to inform NCHSR of this impending article simply because the CDC had not informed the NCHSR?

A. I don't know whether they did or not. They may have informed him. He may have known about it from CDC. I think it was Mr. Eccleston's contention that since we knew about it and since we have in common cases with CDC and it was about kidney dialysis, we would let him know so we wouldn't be accused of knowing something that wasn't communicated to him.

Q. Did Mr. Eccleston relate to you that he or perhaps someone else on your staff had in fact successfully gotten the CDC to change the text of that article?

A. I don't remember whether we did or not.

Q. Do you have a definite recollection that you did not?

A. No.

Q. Do you know for certain that someone else on your staff did not?

A. I know I had no influence or I was not in communication but it is quite possible that the staff may have been in communication with CDC. It is not unusual or surprising because we have had—problem areas have come up on products we are aware of and they are generally sensitive to any wording that might be related to—the sensitivity of our wording. They listen.

Q. And Mr. Eccleston, he would have taken care of this?

A. Probably; he may have gotten Dr. Hefner, who is our Office of Health Affairs, to do the communication because—normally, that is. Dr. Hefner is a physician. Mr. Eccleston is not.

Q. Did you by chance discuss this article during its production during the week of June 22, with Dr. Marshall?

A. I don't think I did.

Q. Did you discuss it with him following the publication, up to the present?

A. I don't think so.

Q. I would like to share with you a June 25, 1986, note to the Commisisoner from Mr. Benson updating the Commissioner on several issues relating to the infection outbreaks in dialysis clinics that practice reuse. Why don't you take a minute to look at that, if you will.

Of course I would like to know if you had seen that prior to your appearance here today.

A.Yes.

Q. Did Mr. Benson generate this note?

A. I don't know. I would have to look at it. Bob may have done some of it.

Q. Bob?

A. Eccleston, excuse me.

Q. Did Mr. Benson clear this note to you prior to it being forwarded to the Commissioner?

A. No.

Q. Is it not common practice for him to communicate with the Commissioner without your knowledge?

A. No.

Q. Sure. Is it not without my knowledge. He usually discusses it without my knowledge. If I am out of town, he may discuss it with me. Or as a result of a discussion with the Commissioner, he may followup.

Q. In paragraph 3, the note states "We have been told that CDC plans to release the article this Friday. Our staff have been in contact with both the authors of the article and reviewing officials and suggest some changes to bring it in line with the statements about dialysis reuse by Dr. John Marshall and John Villforth at the congressional hearings on this subject this past March."

Do you know how the MMWR article was brought in line with your testimony and that of Dr. Marshall at the March 6 hearing?

A. No, I don't remember.

Q. Did you ever at any time discuss how it might have been brought in line with anyone on your staff or at NCHSR or anyone in the Public Health Service?

A. I may have but I don't recall that this was a particularly significant point.

Q. You think you may have?

A. I don't remember.

Q. If you had discussed it, who likely would you have discussed it with?

A. This point?

Q. Yes.

A. Jim Benson or Bob Eccleston.

Q. I want to share with you draft No. 1 of the MMWR article and as we pass it to you, I want you to note, if you would, that this was a facsimile transmission addressed to Dr. Fernando Villarroel, Office of Device Evaluation, CDRH. That is your Center?

A. Right.

Q. The date of this transmission is June 23, 1986, and the transmission is from Steven Solomon, M.D., CDC. Do you know Dr. Solomon?

A. No.

Q. If you turn to page 3 of draft No. 1, that is the very first draft, to the editorial note, fifth line from the top of the page which reads as follows: "There are, however, no controlled clinical studies validating the safety or assessing the risk to patients of the practice of reuse of disposable hemodialyzers, nor are there controlled clinical studies comparing the morbidity and mortality of patients being dialyzed with new dialyzers with that of patients being dialyzed with reprocessed single use only dialyzers."

If you turn to page 3 of draft No. 2, you will find that that statement has been dropped, that particular statement in draft 2 has been dropped. I think Nurse Reed's name is on draft 2. Do you see that, Marie Reed?

A. Yes.

Q. Now are you on page 3?

A. Yes.

Q. Do you note that that statement has been dropped?

A. Let me get calibrated again.

Q. Take your time.

A. I lost track.

Q. Editorial note, draft No. 2, compare the editorial note in draft No. 2 with the editorial note in draft No. 1 and the statement regarding there not having been controlled clinical studies has been dropped in draft No. 2, has it not?

A. Yes.

Q. Now wouldn't the dropping of this statement from the article have brought it more in line with your testimony on March 6 wherein you indicated that clinical trials were not necessary because of the history of clincial experience? Would it not have brought it more in line with your testimony?

A. I don't think so. The statement—the question here is is the statement, there are no controlled clincial studies validating the safety or assessing the risk to patients of the practice of the reuse of disposable hemodialyzers nor are there any controlled clinical studies—that is, I think, a true statement.

Q. You don't quibble with this statement?

A. No; I don,t know why it is necessarily related to the testimony. This is a statement of fact.

Q. I can explain that to you. I did partially, and the first part of the explanation is in your testimony. You indicated, as well as Dr. Marshall, that clinical trials were not necessary because of the history of clinical experience. Don't you recall that?

A. The history of clinical experience is different, of course, and we qualified that, the difference between clinical experience and clinical trials.

Q. That is correct, and as a result of you citing the history of clinical experience, you use that for stating that clinical trials were not necessary. Did you not?

A. I think we said it would be based on—yes, clinical experience.

Q. And then in the testimony I think you recall that Dr. Marshall emphasized that mortality and morbidity within the population of dialysis patients had remained unchanged. Do you recall that?

A. Yes; as a matter of fact, the limited observations, clinical observation in the United Kingdom shows there is a benefit to reuse in terms of morbidity and mortality.

Q. But the studies in Europe were not controlled clinical studies?

A. They were clinical studies, but not controlled.

Q. That is the point that CDC was making.

A. Yes.

Q. What I am asking you now is, dropping this statement, did this not bring the article more in line with the testimony that you and Dr. Marshall gave on March 6?

A. One can draw that conclusion. I don't think that I would interpret it that way.

Q. Did you, or to your knowledge did anyone else request CDC to strike this statement from the article?

A. I don't think we did. Again, even if clinical studies were desparately needed, I am not sure what impact that would have on FDA.

Q. Are you stating——

A. Unless we put these into class three and then we would require them but I don't know—it is a so-what answer. So what if clinical studies are needed or desirable. It would be nice to have. What does that have to do with FDA and why would we feel—why would we want to have that statement erased or out of there? That doesn't make sense. We wouldn't fund them and we can't require them so what does it matter?

Q. Are you stating that although you had nothing to do with striking this particular passage from the editorial note, that you are not certain that someone on your staff might have had something to do with striking this?

A. That is possible. I did not. I don't know what benefit this would have done to FDA.

Q. Who likely would have, if someone had asked the CDC to drop this passage from the editorial?

A. I don't know.

Q. Would it have been Bob Eccleston?

A. Most likely Bob or Jim or I—I can't imagine that the other recipients, Dr. Villarroel or Marie Reed would have necessarily been concerned about it.

Q. They couldn't have taken that responsibility, could they, on their own?

A. They might have. Normally that process would go through Dr. Hefner. She is our contact person.

Q. Dr. Hefner.

A. Marlene Hefner, Director of Health Affairs. We trust in that office the relationship with CDC

Q. Could you check those drafts to see if you see her name anywhere? That name is not familiar with me.

A. I don't know where I would see it.

Q. On the fascimile page.

A. It was sent in to Dr. Villarroel, which is our office and Marie Reed. It is strange why these would have gone to two separate offices. I don't know that.

Q. If you would, turn back now——

A. It is just surprising that it would go to two separate offices and why one didn't come back to the same office.

Q. If you would turn back to page 3 of draft No. 1, the fifth line of the last paragraph. Do you have it before you?

A. There are, however, no Federal standards——

Q. There, are, however, no Federal standards for ensuring the functional or microbiologic quality of single use only hemodialyzers reprocessed in hemodialysis clinics.

If you will check drafts 2, 3, and 4, you will find that this statement was carried forward in each of those drafts all the way through to draft four but then does not appear in the final publication. If you want to look through those to make sure of that—we are in recess for about 5 minutes.

[Discussion off the record.]

Mr. MICHIE. We are back on the record.

By Mr. MICHIE.

Q. Mr. Villforth, have you had an opportunity to review each of the drafts as well as the final publication of the MMWR of June 27, 1986?

A. Yes.

Q. And does that statement that I read a moment ago about there being no Federal standards, does that appear in the final publication?

A. No; it does not.

Q. Did you or to your knowledge did anyone else in your Center or elsewhere in FDA ask the CDC to remove this statement from the article prior to publication?

A. I did not, but it is not unreasonable that someone may have suggested that.

Q. Who most likely would have suggested that, in your opinion? Would it have been Bob Eccleston?

A. It may have been. I don't know. You would have to ask Bob. If that came from someone, it might have come from Bob, because Bob was coordinating this effort for us.

Q. Who beside Mr. Eccleston?

A. Might have been Jim.

Q. Jim?

A. JIM BENSON. I doubt it though.

Q. Did Mr. Windom or anyone else impose a deadline of August 6 for NCHSR to submit the assessment report to Dr. Windom?

A. I understood there was a deadline but I don't know who imposed it—I assume he did, or it may have been Dr. Macdonald and it was right in the transition so I don't know.

Q. Let's go back to June 10, 1986. It was on that date that Dr. Macdonald, then Acting Assistant Secretary for Health, sent a memo to the Under Secretary, Mr. Newman, the subject of which was reuse of hemodialysis devices. We are passing that on to you now.

Have you ever seen this memo prior to your appearance here today? I am sorry, it is a rather poor copy but it is what was given to us. I think that was provided to us by the Department.

Have you ever seen this memo before?

A. After awhile they all look like alike. I must say that doesn't strike me.

Q. Let's turn to page 2 of the memo, if you would to item No. 5. The second sentence of that item states, "NCHSR/HCTA has found no evidence contradictory to the position which we took in testimony," meaning the testimony on March 6 before the Senate Aging Committee.

Was this a true statement at that time, at the time of this memo?

A. I thought so. It was certainly true, as I said—Marshall more recently stated, having had an opportunity to see all the material and to understand some of these issues, I think he is saying, we wouldn't have changed the testimony but at the time when all this flood of material came in I didn't have an opportunity to review it and I think that is what resulted in his earlier memo. Gee, here is a volume of stuff that I haven't had a chance to screen. Therefore I better say—raise some questions.

Now that he has had a chance to see it, I don't think he feels there is any change in the testimony. Yes, that would be my understanding.

Q. Your understanding being?

A. That there was no reason to change the—the new information does not change the position or testimony that was made on March 6.

Q. I would like to share with you a copy of Dr. Marshall's August 11 cover memo for Dr. Windom's signature under which he transmitted the assessment report to Dr. William Roper, Administrator of HCFA, and along with that cover memo is the report itself?

A. Windom's report——

Q. Windom's memo to Dr. Roper.

A. Yes.

Q. August 11?

A. Yes.

Q. And attached to that is the report itself?

A. Yes.

Q. Did you have occasion to review and to comment on this memo prior to it being forwarded to Dr. Roper?

A. How could I forget something so quick as this?

[Pause.]

A. There is no question I had seen it.

Q. Prior to it being forwarded to Dr. Roper?

A. Yes—or I had heard about it, because this was not the approach I think that we wanted to take.

Q. That was not the approach you wanted. In other words, that memo——

A. I wanted to add something else in this. I wanted to have the Assistant Secretary for Health——

Q. What did you want to add?

A. To make a commitment to help, more positive commitment to help HCFA.

Q. In what respect?

A. In terms of the AAMI types of guidelines, AAMI kinds of standards to be put into guidelines for the inspection—State inspection of the providers.

Q. Why did they not accept your suggestion? Could it possibly have been because they knew that the AAMI recommended practice only attempted to address dialyzers and not the blood lines, the transducer filters and the caps?

A. Absolutely not.

Q. Are you certain of that?

A. I think so—no, I am not certain. I don't think they would have appreciated the difference.

Q. Who is they?

A. Whoever was drafting this. Whether it was Bruce Artim. I had some discussions with Bruce Artim on this.

Q. Are you not aware that that memo was drafted by Dr. Marshall?

A. This memo? I may have been. I don't remember.

Q. I would like to share with you a copy of the control version of the memo. You find at the bottom of the page there is a listing of the preparer as well as the revisers, with you listed as one of the revisers. The listing further indicates that you and Mr. Eccleston of your staff and Mr. Riseberg, chief counsel for Public Health Service, as well as representatives for NIH and CDC met on August 8 with Bruce Artim of Dr. Windom's staff. Is that correct?

A. Yes.

Q. In fact the listing includes 11 revisers of a one page memo, including Dr. Windom himself. Was this not an extraordinary procedure for so many people including the chief counsel for PHS and the Assistant Secretary for Health to be involved in drafting this one page memo?

A. There may have been a lot of misspelled words.

Q. Was this not extraordinary?

A. Yes.

Q. Can you explain why this memo was so important to have received such a high level of review and scrutiny from so many people from four different agencies?

A. No, except the meeting was taking place, and everybody was down there and had a chance to put in their 2 cents worth.

Q. Is it not the case that the importance of this memo as evidenced by the amount of attention it received was linked to HCFA's intention to publish 4 days later on August 15 its final regulation to reduce dialysis reimbursement rates? Is that not the occasion?

A. I don't recall that we knew that that was coming that soon and that this was an attempt to beat the clock. I don't think I was aware of that.

Q. Regardless of whether you knew how soon it was coming, was not the importance of this memo as evidenced by the amount of attention it received linked with HCFA's intention to publish?

A. My understanding was that there was a concern on the part of HCFA that the Department assessment report not say something inconsistent and there was a need to transmit that information to HCFA.

Q. What do you mean?

A. Inconsistent with what approach HCFA might be taking in their final Federal Register publication.

Q. Was this memo in fact revised to the extent that it did not conflict with HCFA's publication?

A. I don't think that the original one was inconsistent and I don't think the final one was inconsistent. I don't think all of these reviewers are an indication that it was changed to be consistent with HCFA.

Q. I thought you just said that the reason for all of this revision and revising and so on, was to make sure that it was consistent with HCFA's publication?

A. The concern was—no, not to make it consistent with HCFA's publication, but to give HCFA an understanding of where the Department was coming from so they could make up their mind. I don't think that we knew at the time that HCFA had cut on where they were coming down finally but rather this was an attempt to give them the information—the tools to draw their final conclusion, HCFA's final conclusion.

Q. Which was?

A. That they went out and lowered the reimbursement rates.

Q. Getting back to your meeting with Mr. Artim on August 8, Mr. Artim, as I understand it, is on Dr. Windom's staff. Is that correct?

A. Yes.

Q. Was the purpose of this meeting to discuss revisions of this memo?

A. I guess a part of the discussion had to do with the document itself and the recommendations because there was much confusion, at least in my mind, and I thing in our Commissioner's mind as to whether the recommendations were part of the memorandum—the two-page recommendations that were prepard by Dr. Marshall as to whether they or were not a part of the basic assessment report and whether or not the earlier memorandum which Dr. Windom had sent around to the agencies asking for comment, a reaction to the recommendations, whether in fact we were to make comments on the basic report, whether that as up for discussion, whether the result was penultimate or whether it was a final report, whether the recommendations attached were Dr. Windom's recommendations because there was no title, date, identification, other than it was two pages worth of recommendations. Unfortunately what was missing in the transmittal to us was a—the transmittal memorandum from Marshall to Windom which identified that as two separate pieces of paper——

Q. But nonetheless connected?

A. Yes, but attachment A, and attachment B, and not part of the same report, and it looked like when it came to us from Dr. Windom that it was an Assistant Secretary of Health recommendation, rather than a John Marshall recommendation, so there was some confusion.

Q. Was this common practice, to separate the recommendations from the findings in a report?

A. There is no common practice. This is a different kind of a thing. In the normal assessment report that Marshall prepared are consistent—the ones I have seen are consistent with this format.

Q. In the second paragraph of the final version of the memorandum it is stated,

> The findings to date indicate that when physicians and facilities execrise appropriate quality control over reprocessing of dialyzers, patient outcomes appear to be no different in facilities that reuse dialyzers than for those facilities were single use is the normal operating mode.

Now can you show me where this statement can be found in the findings and conclusions of the assessment report itself and please take your time to assist you in finding the conclusions?

Would you like to examine that carefully because we want to appreciate fully the text of this memo that went to Dr. Roper. Page 53, beginning of the findings and conclusions. They go on for several pages.

A. The point you are making is what?

Q. I am asking you whether or not you can find anything at all within those findings and conclusions that resembles the statement in the cover memo that was sent to Dr. Roper?

A. I don't know whether I could and it would take me some time to study it.

Q. Take your time. There are not that many pages there.

A. Those are the conclusions—you are asking me——

Q. The findings and conclusions are on page 53.

A. You are asking me to find something in the report——

Q. No, no. I am asking you to search the findings and conclusions to see if you see anything at all that resembles the language I read to you from the cover memo. That is all I am asking you, nothing more. There are five pages of findings and conclusions, double spaced, beginning on page 53.

A. Well, by looking at the headings of these particular roman numeral paragraphs and without reading them through thoroughly, I suspect you are correct that one could not find an identical statement or a similiar statement to this contained in pages 53 through 57.

Q. Please, bear with us, take your time and read the next, even if it takes you 5 minutes because we want you to be satisfied——

A. I don't think it is important to me to satisfy myself that these are present or absent in the findings and conclusions, if the thrust of that statement is consistent with what Marshall believes and what might be reflected in the report in its totality. The fact that it may or may not be included in the findings and conclusions may or may not be appropriate or significant any more than the fact that there is nothing in this report that suggests that GMP's should be—that FDA should promulgate the GMP process. That does not appear in the findings and conclusions. Yet those recommendations appear in the recommendation sheet. One cannot track those recommendations to this. Dr. Marshall, for whatever reason, thought that was significant and thought that was a conclusion that he could draw from the report and from other observations.

Q. To your knowledge was this language that I just read from the cover memo Dr. Marshall's language or was it a revision perhaps by you, perhaps by 1 of the other 11 revisers of this 1-page memo?

A. No. I did not—I don't recall making that statement. I don't think it is—I don't know whether it is Marshall's original language. Do you have the original document?

Q. The original document, the August 7 version?

A. No; we don't have that. If I may make a suggestion to you—have you read this report?

A. No.

Q. May I make a suggestion? Why don't you over the next few days take the time to read the entire report and then come back to us and tell us whether or not you can find anything anywhere in that report, in the body of the report, in the findings and conclusions or anywhere else in the introduction that would resemble in any way the statement that I read to you that is contained in the cover memo to Dr. Roper. Would you do that for us?

A. Sure.

Q. That same paragraph in Dr. Windom's——

Mr. SCARLETT. May I raise a point? If it is a part of this interview slash deposition, Mr. Villforth will be glad to do anything but I would object to your asking him to undertake other obligations without going through the channels that Mr. Dockside has discussed with you.

Mr. MICHIE. Mr. Scarlett, Mr. Villforth has just agreed to volunteer, as he did in coming here today, to read the entire report and to get back to us on whether or not he can find anything in that report, regardless of where it may be, that resembles the statement contained in the cover memo. Do you have a problem with that?

Mr. SCARLETT. Yes. I think you are taking advantage of the process that you know should be made through Mr. Dockside. I also object to the nature of the request because the document will be made part of the record and anybody can determine for himself or herself whether the conclusions in the memo correspond to what is in the report.

Mr. MICHIE. I think we would prefer to have the witness give the answer.

Mr. SCARLETT. I understand you would prefer that. If you want to direct the request to Mr. Dockside, I will act as an intermediary and transmit that to him.

By Mr. MICHIE.

Q. I take it you personally would have no objection to doing this, right?

A. I would rather not do it. The point is I am under oath and this would presumably be recessed and you can call me back and I would be sworn in and I would answer the question.

Q. I thought I understood you to say, prior to the note Mr. Scarlett wanted on the record, that you had no problem with reviewing this report and coming back with an answer. Didn't you state that?

A. What I was assuming was that you would bring me back here, swear me in, redo it—when we are through today we would be recessed and you would have an opportunity to bring me back and continue this interrogation.

Q. There are other options. You could provide us with your answer in writing, if you wish.

A. In terms of that approach, Mr. Scarlett's approach would be those sorts of requests would go through Mr. Dockside. If you want to bring me back here and reexamine it, that is what I had in mind.

Q. That same paragraph in Dr. Windom's cover letter also contains the following statement:

> The absence of reported increases in the morbidity and mortality given increased practice of reuse suggests that virtually all facilities are following adequate procedures.

Again, I would ask you to examine the findings and conclusions in the report beginning on page 53 and tell me whether or not you can find anywhere in those findings and conclusions anything at all that resembles the statement that I just read to you from the one-page memo dated August 11 to Dr. Roper from Dr. Windom.

Please take your time.

[Pause.]

A. In scanning the material on pages 53 through 57 I don't see any specific wording——

Q. Do you see anything at all that resembles that in any way?

A. No, not specifically, no.

Q. Page 53 through page 57, that being the page that contains the last paragraph on findings and conclusions, No. 7, roman numeral No. 7. Is that correct?

A. That is correct.

Q. I want to remind you, Mr. Villforth, that you are subject to recall in this deposition. Until such time as you may be recalled, this deposition is in recess until further notice.

Thank you gentlemen.

[Whereupon, at 4:40 p.m., the taking of the deposition was concluded.]

UNITED STATES OF AMERICA

Congress of the United States

To John C. Villforth, Director, Center for Devices and Radiological Health, Food and Drug Administration, U.S. Public Health Service, U.S. Department of Health and Human Services,

Rockville, Maryland, **Greeting:**

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* September 4, *19*86, *at* one *o'clock* p.*m., at their committee room* SD-G33 in the Dirksen Senate Office Building, *then and there to testify what you may know relative to the subject matters under consideration by said committee.* in sworn deposition to be conducted by committee staff.

Hereof fail not, *as you will answer your default under the pains and penalties in such cases made and provided.*

To James F. Michie, Chief Investigator, *to serve and return.*

Given *under my hand, by order of the committee, this* 14th *day of* August, *in the year of our Lord one thousand nine hundred and* eighty-six.

John Heinz

Chairman, Committee on Aging

UNITED STATES OF AMERICA

Congress of the United States

Notice of
Senate Deposition

To John C. Villforth, Director, Center for Devices and Radiological Health, Food and Drug Administration, U.S. Public Health Service, U.S. Department of Health and Human Services,

Rockville, Maryland, **Greeting:**

Please *take notice that at* one *o'clock* P.m., *on* September 4, *19*86, at Rm. SD-G33, Dirksen Senate Office, Bldg., Washington, D.C., J.F. Michie, D.G. Schulke & C.C. Jennings, *of the staff of the* Special *committee on* Aging *of the Senate of the United States, will take your deposition on oral examination concerning what you may know relative to the subject matters under consideration by said* Special *committee. The deposition will be taken before a notary public, or before some other officer authorized by local law to administer oaths; it will be taken pursuant to the* Special *committee's rules, a copy of which are attached.*

Given *under my hand, by authority vested in me by the* Special *committee, on* August 14, *19*86

John Heinz
JOHN HEINZ
Chairman

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this 25 day of September, 1986, and executed the above certificate in my presence.

Linda G. Mehelich

NOTARY PUBLIC IN AND FOR

____

MY COMMISSION EXPIRES: Notary Public, Gwinnett County, Georgia
My Commission Expires April 25, 1990

MONDAY, SEPTEMBER 8, 1986

Washington, DC.

Deposition of John J. Murphy, M.D., called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 1:10 p.m., before Joyce Northwood, a notary public in and for the District of Columbia, when were present on behalf of the respective parties:

Appearances:

For the Special Committee on Aging:

James F. Michie, chief investigator.

David Schulke, investigator.

Christopher Jennings, professional staff member, Special Committee on Aging, U.S. Senate, room SDG-33, Dirksen Senate Office Bldg., Washington, DC 20510.

On behalf of the deponent:

Richard J. Riseberg, Esq., chief counsel, Public Health Service, room 4A53, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Mr. **Michie**. Good afternoon. My name is James Michie. I'm chief investigator for the Special Committee on Aging of the U.S. Senate. Present with me here today in room SDG-31 of the Dirksen Senate Office Building is committee investigator David Schulke, the notary public and stenographer, Joyce Northwood, and John J. Murphy, M.D., epidemiologist, and officer in the Hospital Infections Program of the Center for Infectious Diseases, Centers for Disease Control, U.S. Public Health Service. Dr. Murphy is accompanied by Richard Riseberg, chief counsel for the U.S. Public Health Service.

On September 2, Dr. Murphy was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging, for the purpose of being deposed by committee staff on this 8th day of September, 1986. A copy of the subpoena and notice of deposition will be made a part of this deposition record as exhibits 1 and 2, respectively.

Prior to being sworn in, Dr. Murphy, I want to remind you that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury. Are you ready to proceed?

Dr. **Murphy**. Yes.

Mr. **Michie**. Would the notary public please administer the oath to Dr. Murphy.

Mr. **Riseberg**. Before the oath is administered I'd just like to make a statement for the record.

Mr. **Michie**. On whose behalf, Mr. Riseberg?

Mr. **Riseberg**. On behalf of the Department and Dr. Murphy.

For the record I am Richard J. Riseberg, chief counsel to the Public Health Service. I have been designated by the Department to accompany Dr. Murphy to this interview. The Department has asked me to indicate that it is volunteering to make Dr. Murphy available in order to cooperate with the Senate Special Committee on Aging in connection with its study of issues related to dialyzer reuse, and that Dr. Murphy is participating in today's interview solely on that basis.

He has been advised by attorneys for the Department that the subpoena recently served upon him is of doubtful legality, and that the Department does not regard his participation to be compelled by the subpoena or governed by its terms. Nevertheless, subject to this understanding, he looks forward to answering any questions you may have.

An issue has arisen at some previous interviews as to the oath of the witnesses. While the Department continues to believe that under the standing rules of the Senate only the Chair or a member of the committee has authority to swear in a witness, in order to cooperate with the committee and avoid any further delay in getting to the committee's substantive concerns, Dr. Murphy has agreed to take the oath in question without conceding to it any legal significance it does not otherwise have.

Also, Dr. Murphy has asked me to emphasize whether or not sworn he would answer truthfully to the best of his knowledge.

Mr. MICHIE. Dr. Murphy, have you been apprised of and have you seen a letter dated August 28, 1986, to Mr. Riseberg from Senator Heinz, chairman of the Special Committee on Aging?

Dr. MURPHY. Yes, I have.

Mr. MICHIE. I'd like to pass this letter over to you and ask you to identify as to whether or not this is the letter to which I just referred?

Dr. MURPHY. That's the letter I've seen.

Mr. MICHIE. When were you given this letter?

Dr. MURPHY. Last Friday or Thursday. I think it was Friday.

Mr. MICHIE. So for the record, are you aware that the chairman of this committee has ruled against both objections of the Department's legal counsel?

Dr. MURPHY. Yes, I am.

Mr. MICHIE. And that the chairman did inform Mr. Riseberg that the subpoena is in fact a valid one and that the oath you are about to take is in fact a valid one? Isn't that the sum and substance of the letter from Chairman Heinz to Mr. Riseberg?

Dr. MURPHY. It says that the subpoena is a valid one.

Mr. MICHIE. All right.

Does the letter also state that the oath is valid?

Dr. MURPHY. I think the oath would be valid in any case.

Mr. MICHIE. Is that your understanding from the letter? Would you like to look at it again?

Dr. MURPHY. Yes; let me look at it again.

OK, it says the oath would be valid as administered by a notary public.

Mr. MICHIE. All right, fine. Would the notary public please administer the oath to Dr. Murphy.

Whereupon, John J. Murphy, M.D., was called for examination, and having been first duly sworn, was examined and testified as follows:

EXAMINATION BY THE CHIEF INVESTIGATOR FOR THE SPECIAL COMMITTEE ON AGING

By Mr. MICHIE.

Q. Would the witness please state for the record his full name, age, and current home address.

A. John Joseph Murphy, age 30, 1414 Emory Road, E-M-O-R-Y, Road NE., Atlanta, GA, Zip Code 30306.

Q. With the exception of your having received appropriate and necessary advice and counsel from the PHS Chief Counsel, Mr. Riseberg, and regarding your rights as a witness in this deposition, has anyone prior to your appearance here today attempted to influence in any way your testimony in this deposition?

A. No.

Q. Prior to your appearance here today you were requested to bring with you your log book for 1986. Do you have this with you?

A. I have two log books that were—in which I took notes pertaining to investigations of dialyzer reuse. Those are the ones I brought.

Q. Do you have them with you here?

A. Yes. Would you like me to take them out?

Q. Please, if you would. Would you pass those down the table to me please.

For the record, you have one bound log book labeled as a record of telephone calls; is that correct?

A. Yes. And actually it started out as a record of telephone calls, but I did later use it as an investigation record.

Q. And then you have here a smaller ledger which does not have a——

A. I think on the side it might say "Hemodialysis" there.

Q. Dialysis. Was this smaller ledger used solely for log entries pertaining to your inspections and activities in dialysis clinics?

A. Yes. After the other one was filled up, I used that. And it was only used for hemodialysis.

Q. So the larger book, labeled "Record Telephone Calls" was first, and then this came second?

A. Yes.

Mr. MICHIE. I'll just leave those there if you don't mind.

Mr. RISEBERG. Just a process question, you're not planning to retain them at this point, are you?

Mr. MICHIE. Not at this point. But we may want to take a recess at some point to review them.

By Mr. MICHIE.

Q. Are you a Public Health Service officer?

A. Yes, sir.

Q. For how long a time have you served?

A. About 14 months.

Q. And what is your rank?

A. O4 surgeon.

Q. Briefly, if you will, what is your academic and training background, Dr. Murphy?

A. I am a medical doctor and trained in internal medicine.

Q. Are you board eligible?

A. Yes, sir.

Q. Have you taken the boards?

A. Yes; I took them.

Q. And are you board certified?

A. No.

Q. For the sake of saving time, we will during the course of this deposition refer to your agency as the CDC; the National Center for Health Services Research and Health Care Technology Assessment as the NCHSR; the Office of Health Technology Assessment within the NCHSR as OHTA; the Food and Drug Administration as the FDA; FDA Center for Devices and Radiological Health as the Center; the National Institutes of Health as NIH, the Health Care Financing Administration as HCFA, H-C-F-A, HCFA; the Public Health Service as PHS; Department of Health and Human Services as the Department; and the Association for the Advancement of the Medical Instrumentation as AAMI, A-A-M-I.

Could you briefly now for the record, Dr. Murphy, describe the function and mission of the Centers for Disease Control?

A. As far as I understand it, the purpose of the Centers for Disease Control is to conduct research and investigations to prevent disease as much as possible. They have a number of functions that are under that, but briefly that's their function.

Q. Does this also include making determinations on whether or not controlled clinical study would be required in any particular aspect of medicine?

A. I'm not sure that that's an officially prescribed function. But I'm sure in many situations that judgment is made by the CDC people.

Q. And does not the expertise necessary to make such a recommendation reside within the CDC?

A. I think probably yes.

Q. If you could tell me what do you mean by probably?

A. You asked whether the expertise is there to make that recommendation. I think yes.

Q. Does not the CDC include personnel such as yourself, an epidemiologist, and additional personnel of your background and expertise, in order to make determinations on suspected problems with regard to epidemics, whether these problems are concerned with disease or whether they are concerned with procedure and process in any aspect of medical practice?

A. I'm not sure I understand exactly your question.

Q. For example, doesn't the CDC contain the necessary expertise, necessary individuals with the expertise in epidemiology, internal medicine, and other areas of the medical profession in order to determine as to whether or not certain studies should be done that would pertain to process and procedure in medical practice? And I'll name one specific thing, that would have to do with the reprocessing and reuse of medical devices?

A. I think, yes, that the expertise is there to recognize studies that have been done or to direct further studies as to safe procedures. And that would also include hemodialysis.

Q. And to your knowledge hasn't the CDC participated and hasn't—and I'm talking about in the issue of reprocessing and reuse of medical devices overall, hasn't the CDC participated in the past in the study of this particular issue as well as in the making or recommendations on what needs to be done in the formulation of policy and in ensuring the safety and well-being of patients?

A. Yes, they have participated. I'm not sure of what you asked about policy. The CDC makes recommendations, guidelines.

Q. From which perhaps policy flows?

A. Perhaps.

Q. Now, could you briefly describe the function and mission of the Hospital Infections Program?

And before you do that I'd like for the record to reflect that Mr. Jennings, C.C. Jennings, is now present, a staff member of the Special Committee on Aging.

By Mr. MICHIE.

Q. Again, Dr. Murphy, what is the function and mission of the Hospital Infections Program?

A. There's a number of roles. First of all, from my perspective that is to act as a consultant and investigatory team to assist State health departments, local health departments, and individual hospitals in control of hospital infections or epidemics thereof.

There are several other branches that entail different functions. There's a guidelines branch that would be involved in making guidelines, recommendations to hospitals. There's a laboratory branch that's involved in a lot of different areas of laboratory consultation, laboratory research. And then there's an attempt to do some sort of national surveillance of hospital infections, and that's a large part of the branch—of the programs activities.

Q. And what's the specific—specifically what is the mission and function of the epidemiology branch?

A. Essentially as a consultant role to conduct investigations of ongoing epidemics or suspected epidemics and to do telephone consultation to State and local health departments and individual hospitals or health care facilities in an attempt to control epidemics.

Q. And you are within the epidemiology branch?

A. Yes.

Q. How many other personnel with qualifications similar to yourself are there in the epidemiology branch approximately? How many epidemiologists?

A. There's about eight.

Q. About eight epidemiologists?

A. Yes.

Q. About how long a time have you served as an epidemiology investigator, Dr. Murphy?

A. About 14 months.

Q. And could you describe for us over those 14 months what's been your function and responsibilities?

A. My primary function is as a telephone consultant, which I would be taking telephone calls from any member of the public that calls with questions regarding hospital infections. Usually hospital infection personnel, State health department personnel, other Federal agencies. It could be—the phone calls from a number of sources, laboratory personnel with questions.

Q. Do you sometimes—I'm sorry, go ahead.

A. Then besides that really my primary role is I think a field investigator, to go out when we are invited to conduct investigations. I'm the one that goes out and does them.

Q. You go out to inspect?

A. I go out to assist, to consult, to investigate.

Q. Are you the only person within the epidemiology branch who travels in this way?

A. No.

Q. How many are assigned to that?

A. About three or four.

Q. Who is your immediate superior at CDC?

A. William J. Martone is the branch chief. Although there's three people within the branch that might be my supervisors on any project, and those would be Dr. Martone and the two assistant chiefs in the branch.

Q. And who are they?

A. Dr. Steve Solomon and Dr. Bill Jarvis.

Q. Do you report to both Dr. Jarvis and Dr. Solomon?

A. As of yet I haven't done any investigations where Dr. Jarvis was my supervisor. In general I report to Martone, but sometimes I've been assigned to work with Dr. Solomon specifically. But we all work together kind of as a team.

Q. And during those occasions did you report to and were you responsible to Dr. Solomon?

A. Yes.

Q. Dr. Solomon and Dr. Martone, have they both been there since you came on board?

A. Yes.

Q. What about Dr. Jarvis?

A. Yes.

Q. Now, in the course of your duties and responsibilities, how closely have you worked with Dr. Solomon?

A. Very closely, daily. You know, when I came on to the CDC, I began at the hospitals infections program, and I'd really have to say that a lot of what I've learned and what I know about epidemiology and hospital infections has come from Dr. Solomon and Dr. Martone.

Q. From whom would you normally receive instructions and assignments regarding performance of your duties?

A. Dr. Martone.

Q. Not from Dr. Solomon?

A. Dr. Martone is Dr. Solomon's boss. And generally he's the one who does the administrative assignments.

Q. When you were out in the field, when you're conducting these visits, inspections, who do you consult more closely with, Dr. Solomon or Dr. Martone?

A. It depends who's supervised me in one particular investigation. If Dr. Solomon is supervising me, I consult with him and I take my, you know, orders from him, and I don't have to go to Dr. Martone at all to check on his authority.

Q. Now, specifically within the category of dialysis clinics, let's put the hospitals and the other physical entities aside and let's just talk about dialysis clinics. For the most part in that particular area have you worked closely with Dr. Solomon and have you not received most of your direction from him in that regard?

A. I've conducted four investigations in relation to hemodialysis, and I've been supervised by Dr. Solomon on all of them.

Q. And can you tell us when was the first such inspections you conducted?

A. It was in May 1986.

Q. May? Would it have been May 10, beginning on May 10, 1986?

A. I think it was May 9.

Q. And that would have been where?

A. That was in Inglewood, CA—actually in Los Angeles.

Q. For how long a time to your knowledge, for how long has CDC been conducting these inspections or visits to dialysis clinics?

A. I really don't know when the first one was for dialysis clinics. I know CDC has been in existence about 40 years. I know of some published CDC reports about hemodialysis investigations say 5, 8 years ago. I can't say when the first one was.

Q. But since you've come on board at CDC over the past 14 months, how many other than the 4 you've conducted, how many has CDC conducted; do you know?

A. Those are the only ones that I know of right now. There may have been other ones outside the hospital infections program during that time. They might be assigned to the hepatitis branch if it's a hepatitis problem. But within the hospital infections program those have been the only 4 during my 14 months.

Q. Have there been on occasion over the past 14 months reports of infection outbreaks at dialysis clinics that have not been investigated by you or by anyone else?

A. Yes, yes.

Q. Roughly how many?

A. There have been—I know of at least two others that have—we've talked to people at those centers about them. And one other that I have heard of hearsay, maybe three others that we've talked to on the phone about, and one other I heard of, but about three or four.

Q. Three or four in addition to the four you inspected?

A. Yes.

Q. Is it possible that there have been more than that that you don't know about?

A. More than reported to the CDC?

Q. Either that or a larger number than that that somehow or another CDC learned about?

A. It's possible.

Q. Does CDC plan to visit these three or four other clinics in order to inspect or not?

A. Not that I know of, no.

Q. How often does CDC inspect these kinds of clinics jointly with FDA? What's been your experience with that?

A. In my experience I've conducted four investigations and all of them have been jointly with the FDA?

Q. All? Based upon your knowledge is this extraordinary or is this common or usual practice, for the CDC and the FDA to inspect these facilities jointly?

A. Hemodialysis facilities?

Q. Yes.

A. I think that from the hospital infections program perspective we would always consult with the FDA before embarking on any such investigation.

Q. I can appreciate that, but is this standard operating procedure? Do you know for a fact in the past whether CDC did investigate other cases such as the very tragic case that occurred in Baton Rouge where 15 people died—you're aware of that case; aren't you?

A. Yes.

Q. Was that a joint CDC-FDA undertaking?

A. I don't know if that was a joint undertaking. But I strongly suspect the FDA was consulted before the investigation took place.

Q. But is it common practice though that in addition to consulting with FDA, is it common practice for these two agencies to conduct joint inspection of these two facilities, to your knowledge, based upon what you heard about the institutional background of CDC?

A. It's difficult for me to answer that question. As I said, all the ones I've participated on have been jointly with the FDA. I don't know if there's been others that have not been joint.

Q. Do you know if any of the clinics that experienced dialysis problems over the past year were inspected by FDA without accompanyment of CDC?

A. Yes.

Q. How many?

A. Two, maybe three, or maybe four. I think—you know, like I said, I haven't been in contact myself with all the organizations that had other problems. I think at least three of them were inspected by FDA people.

Q. Can you explain why CDC didn't participate in those?

A. We participate in an investigation when we're invited and when we see the scope of the problem as within our domain and when we see some possible benefit to our participation. And I would say that in those three or four other cases the outbreak there did not meet those criteria.

Q. And if you could be specific, just exactly what are those criteria?

A. Like I said, where we could be of some benefit to the clinic, where the problem is within our knowledge base and domain, and where we're invited.

Q. Now, either——

A. Invited by both clinics and the State and local health departments.

Q. And FDA?

A. Not necessarily.

Q. Now, in these cases did these three or four additional cases involve infection outbreaks?

A. Some of them did and some of were merely pyrogenic reactions or symptomatically similar to infection but not necessarily infection.

Q. Do I take that to mean though that because of your not having participated in those inspections that you really don't know the answer to that question?

A. I don't know the answer to that question. In some of them I know there were documented infections. In others I'm not sure whether infections were documented.

Q. If the State or if the local authorities had invited you to participate in these inspections, would you have?

A. In general if we're invited by the State, if they want us to be there, we will go.

Q. But they have to make the first move? They must call you and say, CDC, we would like for you to assist us in this inspection?

A. No. Sometimes we would call them up and say we're very interested in this, we think we can be helpful, we would like you to invite us.

Q. Did you do that in any of these cases?

A. I don't think that we pushed for an invitation in those cases.

Q. I don't mean pushed. I mean did you suggest to any of those local or State entities that you would be willing to assist them in their inspection?

A. Yes.

Q. You did?

A. Yes.

Q. And how did they respond?

A. And I think the gist of the discussions were that we weren't necessarily needed or the size of the problem did not warrant our participation.

Q. Now, regardless of whether you agreed with that decision on the part of the State, if you're not invited, regardless of whether you agree or disagree with them, you don't go; is that correct?

A. Right, that's correct. Our jurisdiction is only to assist State health departments.

Q. In other words, you have no authority whatsoever, regulatory or enforcementwise, to impose—for the CDC to impose itself upon any hospital or clinic or any medical facility entry for inspection; is that correct?

A. That's true. Now, you mentioned regulatory function. There are some areas of CDC that have regulatory function, but none within the hospital infections program's domain.

Q. Now, with regard to the four clinics that you did jointly inspect with FDA and with the State and local authorities, who was it that extended the invitation to you, you meaning the CDC? Was it the State and local authorities or FDA or both?

A. It was the State and local authorities and dialysis clinic administration. And again, I somewhat object to your use of the word inspect. We do not go in and inspect these places. We go in a consulting role to conduct an investigation, but it's not an inspection per se.

Q. Well, would it be all right if then as we refer to them as visits?

A. Visits, that'd be great.

Q. To assist the local authorities, State authorities, in determining the cause of the accidents; right?

A. Right, right.

Q. Now, in the case of FDA what purpose did you serve in that agency's regard?

A. I don't know what you mean.

Q. Did you also go in to assist the FDA because the FDA does have authority to inspect; does it not?

A. Yes, yes. And in some of those investigations at least, the FDA requested our participation.

Q. They did?

A. Yes.

Q. And so you went in with the FDA; is that correct, at their request and not at the request of the State authorities in some of those cases?

A. No. We always went in at the request of the State health department.

Q. In other words, regardless of what FDA asked you to do in so far as accompanying them on the visit, on your visit and on their inspection, you also had to have an invitation from either the State authorities or the clinic itself?

A. Both.

Q. Both?

A. Both. And we will not go into any facility without the invitation of the State health department.

Q. Could that perhaps explain why, Dr. Murphy, CDC's seldom involvement in visiting, if you will, these clinics to assist in determining the cause of infection or any other respect of medical infirmity?

A. I don't think so. I think in general the States—most States are—you know, will be willing to invite us if we have interest in something, and certainly would be willing to invite us if they feel it's a problem.

Q. Do you have a data base to support that statement, your feeling? In other words, do you have a data base that would memorialize for yourself and for CDC those States that had problems in these dialysis clinics and decided not to invite you and those clinics that did have dialysis clinic problems and did invite you?

A. I don't have any data base other than my own personal experience and hearsay from the people around me.

Q. So would it not be the case that in answer to the question I asked you that in reality you really don't know what's happening out there at the present time; that in fact there may be many, many other cases of the types of infection outbreaks that you had occasion to visit the clinics, but that since they are not reported there's no way for you to know about them; isn't that the case?

A. I suspect that there might be other outbreaks and that they're not reported to us.

Q. When you visit these dialysis clinics, is there a standard procedure that you use for your visit? In other words—let me try and help you with that. What I mean by that is do you have a checkoff list that you use or do you rely upon the guidance and direction of either the State or local authorities or both and the personnel at the clinic?

A. In general there's kind of a theoretical framework that we use in approaching any epidemiological problem, and it's kind of been developed by the CDC over the years, and I would use that. Other than that general framework, I think each situation is potentially unique, and we go in with the ability to conduct the investigation however we choose.

Q. In other words, in a situation like that you need flexibility?

A. Yes, a lot of it.

Q. Based upon your experience over the past 14 months, what would you say are the problems most commonly found in dialysis clinics?

A. Of the clinics that I investigated——

Q. Correct.

A. [Continuing.] The most common problem we investigated was that of bacteremia, bacterial infection of the patient's blood that occurred during dialysis.

Q. Can you now elaborate on the causal effects, what is it that brought this about?

A. I'm not sure exactly what you mean. Do you mean the mechanism whereby they became infected?

Q. Not only the mechanism but the process and procedures. Were there problems that you encountered in your visits pertaining to process and procedures in the reprocessing and reuse of dialysis devices?

A. I think, yes, that the reuse of intravascular devices in these clinics was the major procedure that we were investigating as to the probable cause of these infections.

Q. What was wrong with the procedure and the process?

A. I would say that there's—we didn't know for sure. I would say that there's two possibilities, two major branches of that. One is that the devices were inadequately sterilized, the second is that the membranes of the devices were damaged during the reprocessing procedure, during the disinfection, then allowing bacteria to cross the membrane into the patient's blood.

Q. The damaging of these dialyzer filters—this is what you referred to, is that correct?

A. I don't like the word filter itself. The dialyzer itself is the device we're talking about.

Q. And it contains the membrane?

A. It contains a membrane. And I think membrane is a better word for it there.

Q. Do you also suspect that the number of reuses of this membrane is also in some way connected with the frequency of infection?

A. It think that we showed that clearly in our investigations.

Q. I'm sorry, tell me what is it that you did show clearly in your investigations?

A. In two of the investigations, patients who became infected had higher number of uses of their dialyzers than comparison patients who did not become infected, whether that be in the setting of a case control study comparison or a retrospective cohort analysis.

Q. Now, in addition to that, did you also find in your visits that some of the perhaps fundamental producers and requirements for quality control were deficient? In the overall process, for example, did you find, for example, in all four of these clinics that the procedure for reprocessing, the physical reprocessing of these devices, was in writing and were they followed? What were your findings on that?

A. Well, in—you have several questions there. One, was "was the procedure implicated as the problem?"

Q. As part of the problem?

A. Yes, as part of the problem. In several of the centers we found problems with the procedures.

Q. For example?

A. For example, inadequate filling of the dialyzer, deficiencies in the testing of potency of the disinfectant used to fill the dialyzers, similar problems to that. We suspected though that it was not those deficiencies which was the inherent problem. However, those minor deficiencies somewhat clouded our investigation in that we were unable to say exactly that it was the disinfectant that was the problem. This to some point was our suspicion—that there was some problem with the disinfectant being used—but we were unable to show that because there were minor procedural problems in the filling of the dialyzers, et cetera.

Q. And could these, as you call them minor procedure deficiencies, could they have also contributed to patient injury?

A. Yes; they could have.

Q. Not only in the situations that you investigated, but could this not lead to problems in other clinics as well if these deficiencies exist in other clinics?

A. I think it could.

Q. To your knowledge have any of CDC's inspections of these dialysis clinics been prompted by findings in the annual survey conducted jointly by CDC and HCFA?

A. Not any that I know of, although the people in the hospital infections program who work with dialysis clinics are very active in those surveys and aware of the results of them. But I don't know of any instance where an investigation that we took place in was prompted particuarly by that survey result.

Q. Doesn't this annual survey rely upon voluntary reporting by dialysis clinics?

A. Yes.

Q. Has the accuracy and sensitivity of CDC's annual survey been tested to determine whether it portrays the actual incidence of bacteremia in these clinics?

A. I don't know. I don't—well, for example, the studies that you showed me before this hearing could be used to validate that information, but I'm not—other than that though, I'm not aware of any validation that's been enacted to test that survey result.

Q. If there were, would you be aware of it?

A. I might or I might not.

Mr. MICHIE. Let's take a 5-minute recess. We need to retrieve a document at the present time. So we're in recess now.

[Short recess.]

Mr. MICHIE. We are back on the record.

By Mr. MICHIE.

Q. Dr. Murphy, I'd like to share with you a June 20, 1986, letter to Dr. Enrique Carter who is Director of the OHTA at NCHSR. This letter is from Gary M. Noble, M.D., Assistant Director for Science at the CDC.

Please note in that letter that Dr. Noble informs Dr. Carter that indeed the survey has not been tested or has not been assessed in order to determine the actual incidence of bacteremia in these clinics.

Let the record show that Dr. Murphy is reading the letter in its entirety, the letter to Dr. Carter from Dr. Noble.

A. OK.

Q. As a matter of fact, would you verify for me that that letter states, quote: "The sensitivity of this surveillance system has not been assessed." Then it goes on later in the letter to state: "We have no data on the reuse of blood lines, transducer filters and dialyzers caps?"

A. Yes; it does say that.

Q. It goes on to say: "There are no guidelines or recommendations that extend to these devices;" is that correct?

A. True.

Q. Would you think that Dr. Noble would be in a position of authority to be able to state what he did in his letter to Dr. Carter?

A. Yes.

Q. He would?

A. I would think he would; yes.

Q. Is it true, Dr. Murphy, that because CDC has not included in their surveillance activity any specific questions dealing with increased rates of bacteremia associated with reuse of dialysis disposables, there is no data covering this potential hazard on a national basis; is that a fact?

A. I would say, yes; that's a fact.

Q. Can you tell me please why you believe with certaintly that this is a fact?

A. It's because there isn't—if there's no information on the nationwide scope of the problem.

Q. Have you asked about this? Have you asked about this in the past? And were you told that there is no data on a nationwide basis?

A. I've looked for information on that and have found none.

Q. Prior to your appearance here today and anyone within PHS shared with you a copy of the NCHSR's August 6, 1986, health technology assessment report on the safety and efficacy of the reprocessing and reuse of dialysis disposables?

A. No.

Q. Were you aware of its existence?

A. Vaguely.

Q. If so how did you come to learn of it?

A. I have heard mention of it in passing by some people only with relationship to the investigations that I had done.

Q. I'd like to share with you a copy of that report. And at this time I'd like you to take a few minutes to read through the findings and conclusions beginning on page 53 if you would.

A. OK.

Q. Page 53. Take your time please.

A. Would you like me to read all of these?

Q. Yes, from page 53 through to the middle I think of page 57, page 57. I think that's where they end.

A. OK.

OK, finished.

Q. Let me share with you now copies of—photocopies of entries in a log recently provided to this committee by CDC. Are these your log entries?

A. No.

Q. If not, examine them if you would and try to identify for us, if you can, the authors of these entries at CDC.

A. OK, I believe that they're Steve Solomon's.

Q. Dr. Solomon?

A. Yes.

Q. If you would turn——

A. I can't be sure, but I would guess.

Q. I understand. If you would turn to—let me find the page for you. This is—I don't recall the page here. There's an entry here that I think could possibly pinpoint this definitely. This entry dated August 4, 1986?

A. Yes.

Q. If you would read that and tell me if that gives you a clear picture of who these notes belong to. I think it memorializes the fact that you along with several other parties were in a telephone conference.

A. Yes. So this I would say definitely means it's Dr. Solomon's notes.

Q. Thank you. Why don't you just hold on to those over there with the report itself.

A. OK.

Q. Now, I'd like to share with you a memo to the hospital infections program director at CDC from you and Dr. Steven Solomon. The subject of this July 8, 1986, memo is "Epidemic Aid Investigation of Bacteremia Associated with Reuse of Disposable Hemodialyzers." Do you recall this memo?

A. This is a draft of a memorandum that was, I believe, never sent.

Q. Do you see draft marked anywhere on it?

A. Well, I see that it has a Wang document number on it which would not go out on a final product.

Q. So what you're suggesting——

A. And I know that I never signed a copy of this.

Q. Did you write—did you draft that?

A. Dr. Solomon discussed it with me a little bit, but Dr. Solomon drafted this.

Q. Was this memo drafted after you had inspected several of these clinics wherein there were infection outbreaks involving patients, these having occurred in April, May, and June of this year?

A. Yes. So this would have been after two of them, the ones that occurred in May and June. There was none in April. There was no investigation in April.

Q. Please turn to page 2 of the memo, down in the summary paragraph, titled "summary," it reads as follows, quote:

> It is evident that the data base concerning the safety and appropriateness of reuse using disposable hemodialyzers is currently inadequate to make a scientific assessment of whether or not this practice should be promoted, tolerated, or prohibited for public health purposes. Even if the practice itself is found to be safe (or even beneficial), there is an obvious need for standards which must be based on clinical trials and incorporate long-term assessments of patient outcomes using a variety of measures, including morbidity and mortality.

Am I correct, Dr. Murphy, in interpreting this statement to mean——

A. That's not exactly how it is written here.

Q. I left out a few words.

A. Yes, you did leave out a few words.

Q. "Obvious need for standards," and then I jumped to the next sentence which much be based—did I take anything out of context?

A. No.

Q. Am I correct in interpreting this statement to mean that you and Dr. Solomon believe that the data base suffers from serious inadequacies?

A. I think that you are correct in interpreting that. We believe there's inadequate data.

Q. Inadequate data with regard to this particular issue?

A. Yes.

Q. And so as a result of that, both you and Dr. Solomon believe then—and correct me—still believe today that the data base concerning the safety and appropriateness of reusing disposable hemodialyzers is currently inadequate to make a scientific assessment of whether or not this practice would be promoted, tolerated, or prohibited for public health services.

A. I think certainly if we had more information we could make better decisions and better conduct investigations of outbreaks.

Q. I understand. But, as it is stated in the memo, was this not your belief then and is it still your belief today?

A. I still believe as is stated in that draft of the memorandum, that there could be more information obtained.

Q. In order to determine whether this practice should be promoted, should be even tolerated, or prohibited for public health purposes; is that correct?

A. Right.

Q. Then you go on to state: "Even if the practice is found to be safe—or even beneficial." Does this not indicate that you have some doubt as to the safety or beneficiality of this practice?

A. Yes.

Q. And what is your doubt based on?

A. Our doubt I think is based on a large amount of experience with intravascular devices and the experience that there have been other outbreaks associated with inadequate disinfection of them. By these I refer to other devices used in hospitals, intravascular transducers, intravascular catheters. It's difficult to disinfect these devices and when you have a day-to-day operation there's frequently problems or inadequacies in disinfecting them.

Q. As a matter of fact, is it not the case, Dr. Murphy, that your branch, epidemiology branch, has for years been concerned with regard to the reprocessing of these disposable devices, not just dialysis, but these other devices you mentioned, and don't you in fact have in your files hundreds of cases of accidents and malfunctions of these devices overall, not just dialysis devices but other disposable devices as well?

A. I don't know about hundreds, but there are other investigations conducted with respect to reuse of used devices. And some of them were concluded to be due to inadequate disinfection.

Q. So as a result of these findings, not only just in the area of dialysis but also in other areas of the reprocessing and reuse of disposable devices, is it not the case that CDC over the past several years has continued to be and still is concerned about reprocessing of these devices without standards?

A. Continues to be concerned about reprocessing with standards or without standards.

Q. But then you go on to say in your memo there's an obvious need for standards which must be based on clinical trials and incorporate long-term assessment of patient outcomes. My question to you is if you are going to have reprocessing, is it not the case that you must also have standards, standards that are grounded and based upon clinical trials? Isn't that what you state here?

A. Well, like I said, I didn't write this. But, yes; that's the—that's the intent of that.

Q. Do you agree with that?

A. I think that it would be optimal if you had standards based upon clinical experience. I think it's not necessary, I mean it's obviously not necessary because right now we have some standards established and they're not all based on clinical experience.

Q. Whose standards, Dr. Murphy?

A. Well, each clinic would have their own protocols, procedures, standards, established.

Q. Isn't it the case, Dr. Murphy, that at one of the Georgia clinics either you or FDA found that that clinic didn't even have a procedure in writing for reprocessing, isn't that the case?

A. The two clinics that I investigated in Georgia had protocols for reprocessing but they had not been updated based upon their new procedure. So they were effectively outdated.

Q. And was the new procedure in writing?

A. No.

Q. Do you at this time believe that clinical trials, controlled clinical study, should be performed in order to determine the safety and efficacy of reuse of disposable devices in dialysis?

A. From my perspective, it would be easier to make decisions and to conduct investigations if those studies existed or were done. I'm not one to decide whether they should or should not be done.

Q. I'm not asking you to decide, Dr. Murphy, I'm asking you for your professional opinion in light of what you've learned over the past 14 months with regard to the process and the procedure in dialysis clinics. I ask it on that basis. Do you believe clinical studies, controlled clinical studies, should be performed in order to determine the safety and efficacy of disposable dialysis device reuse?

A. I think it would be optimal if they were performed.

Q. What do you mean by optimal?

A. Well, it's a big question whether they should be done because it's going to cost a tremendous amount of money.

Q. Well, we've heard that from other sources in the Department, Dr. Murphy, but let's put cost aside. All we're asking you is to give us your professional opinion——

A. Putting cost aside I think the studies should be done.

Q. Do you not believe these studies are necessary putting cost aside?

A. I think that it would be optimal if they were put—if they were done. I think that dialysis could go on if they were not performed. So therefore they're not necessary. But in the best interests of patient care it would be optimal if clinical studies were done.

Q. Do you believe there is a need for controlled clinical study, which would incorporate long-term assessments of patient outcomes using a variety of measures, should also look at morbidity and mortality?

A. Yes.

Q. You believe that?

A. Yes.

Q. Does Dr. Solomon share your belief in that?

A. I believe he might.

Q. Did he not write this memo?

A. Yes; he did.

Q. Has he changed his mind?

A. This was a draft of a memo that was never sent. I think that he shares my opinion in that point.

Q. Dr. Murphy, I understand. Nonetheless the both of you were aware that we were sent a copy of this memo. So therefore I'm asking you whether or not you've changed your mind since that draft?

A. No; we haven't changed our mind.

Q. Fine——

Mr. RISEBERG. Have you discussed this specific point with Dr. Solomon?

The WITNESS. I haven't discussed this specific point. But we never sent this memo.

By Mr. MICHIE.

Q. I understand that. Regardless of whether you sent it or not, my question has to do with not only what your belief was then but what it is today. And you've given me your answer.

A. Right.

Q. Thank you. Do you recall having participated in a conference telephone call on August 4, 1986, with Dr. Carter, Dr. Erlichman of NCHSR, Bill Martone, Dr. Martone, and Dr. Solomon, regarding the June 27 MMWR article's recommendation that additional studies of reuse were needed? Do you recall that?

A. Yes; I do.

Q. If you would take those log entries there please and turn to page 20. That's the entry we were looking at just a moment ago which helped convince you that those are indeed the log entries belonging to Dr. Solomon?

A. Yes.

Q. The entry dated August 4, 1986, refers to the conference call with NCHSR personnel and contains the following statement. I'm putting in brackets the beginning phrase "[there is] no data on whether reprocessing with formaldehyde or other disinfectants are better, equal to, or worse than single use only." Is that your reading?

A. Yes; that's what it says.

Q. Was NCHSR given this information during the conference call?

A. It's not clear from the note. I suspect we discussed that fact. But it doesn't say exactly how that was stated.

Q. Well, it's in quotes, isn't that in quotes there? Doesn't that indicate——

A. Reference to the June 27 MMWR, yes. It's—well——

Q. Take your time.

A. There is an opening to the quote and there's no closure to it. So I don't know where the quote stops. But I don't think this is the exact wording from the MMWR article.

Q. No; you're correct, Dr. Murphy. So does this not lead you to believe that that piece of information was discussed in the conference call?

A. Yes.

Q. Do you have a recollection of that now?

A. Yes.

Q. Was there any additional discussion about this particular passage: "There is no data whether reprocessing with formaldehyde or other disinfectants are better, equal to, or worse than single use only"? And by the way I was wondering——

A. Nothing specific that I recall.

Q. [Continuing.] Who was it on the other end of the line at NCHSR? Was it Dr. Carter or Mr. Erlichman; do you recall?

A. As I recall, it was Dr. Erlichman. It says Enrique Carter, in parentheses Martin Erlichman, so I'm not sure who was speaking on the other end.

Q. Did Mr. Erlichman ask you any questions with regard to that piece of information?

A. During that phone call?

Q. Yes.

A. Asked me specifically, I don't recall. I don't recall any specific questions to me.

Q. Let me explain to you why—the significance, at least as we see it, to this particular phone conference. It took place on August 4. The assessment report by the NCHSR was finalized within 24 hours of that phone conference and was forwarded to Dr. Windom, the Assistant Secretary for Health at the hour of noon on August 6.

A. Yes.

Q. So that's why we see some significance to this phone call.

A. Sure.

Q. Was this phone call, was this—did it give you the impression—by the way, did you make the call or did NCHSR make the call?

A. I don't remember. I think they called us, but——

Q. They called you?

A. See, I was like called into the office to participate in the call that was ongoing——

Q. You weren't in on the call from the very beginning?

A. [Continuing.] But I don't remember whether we called them or vice versa.

Q. Why were you called in to the conference? Do you recall?

A. Well, it's just that we were all working on this project. And as I recall, I was sitting in my office, and someone said come on in, there's a call going on with respect to dialyzers. We frequently have conference calls like that, you know, for a topic that we're all working on.

Q. Now, if you compare that notation in Dr. Solomon's log with the draft memo that we just went over a moment ago, is it not the case that the information contained in both is identical insofar as the business about no data if you refer back to that summary paragraph in that memo? They're quite similar; aren't they?

A. They're very similar, yes.

Q. To your knowledge, was this the first occasion, this phone conference on August 4, the first occasion on which CDC had provided this information to NCHSR?

A. We had had previous conversations with them.

Q. You had?

A. But I don't know if that was the first time that we imparted it to them. I mean I know we had talked with them earlier.

Q. Why do you imagine at that late date, before having to produce a report, that they would have called you about this?

A. I would expect they might have been checking up just before finalizing it to make sure nothing new had come in.

Q. Isn't it possible though that this was in fact the first time that that information had been given to NCHSR about the deficiency, inadequacy of the data?

A. Well, we had—I know we had discussed it with them before, the deficiency, inadequacy of data.

Q. But had you ever told them that the deficiency was such that you couldn't even make a decision, a scientific assessment, on whether or not it should be promoted, whether or not it should even be tolerated or whether or not it should go on. Did you ever tell them that?

A. I think that we had expressed to them before this some—our willingness for more studies to look at the safety and efficacy of it.

Q. Your willingness——

A. Our desire for more studies.

Q. Your desire?

A. Yes.

Q. Let me refer you now to the assessment report if I may, to the findings and conclusions you read a few moments ago beginning on page 50.

A. Yes.

Q. I'd like you to locate anything at all in the findings and conclusions that resembles what NCHSR was told in that telephone call with regard to absence of data on reprocessing and reuse in dialysis clinics. If you can find that for me I'd appreciate it.

A. It says here: "The occurrence of bacteremia/sepsis is unknown since . . ."—goes on to some other stuff. So that's one suggestion. "There is no requirement that such complications are reported." "No adequate clinical trials have been performed to address either the short- or long-term safety or efficacy of the practice versus hemodialysis blood lines and tubing"——

Q. What I'm after, Dr. Murphy, is there anything anywhere in those findings and conclusions that states that there are no data on whether reprocessing with formaldehyde or other disinfectants are better, equal to, or worse than single use only? Can you find a sentence or paragraph anywhere in there that conveys the same meaning in toto?

A. Well, I think the sentence I just started to read hits on the same topic. It doesn't say exactly that. But it says "no adequate clinical trials have been performed to address either the short- or long-term safety or efficacy versus the hemodialyzer, blood lines, and tubing, transducer filters or dialyzer caps," period.

Q. Does that convey the meaning that you or someone else stated over the phone on August 4, that there are no data whether reprocessing with formaldehyde or disinfectants are better, equal to, or worse?

A. I think it does.

Q. The same meaning?

A. Yes, very closely.

Q. How closely?

A. It doesn't mention formaldehyde.

Q. Does it mention better, equal to, or worse?

A. That is the intent of any comparison trial. And I think it says no adequate clinical trials have been performed. Well, you would assume that clinical trial is a comparison trial between two branches of an experiment or a study, and their comparison would result in a better, equal to, or worse result.

Q. I can appreciate that you would make that assumption, Dr. Murphy, in your position with your expertise, but what I'm looking for is literal language to the effect of what was stated in that August 4 telephone conference.

And my question to you is: Do you find any of that language anywhere in those findings and conclusions?

A. I don't see anywhere where it mentions the words better, equal to, or worse.

Q. Do you see anywhere in there words to the effect that there are no data on whether reprocessing with formaldehyde or other disinfectants is better, equal to, or worse than single use only? Do you find that conclusions anywhere in those pages?

A. I don't find it stated as you state it, as you quoted there. I don't see the same sentence.

Q. Well it's from Dr. Solomon's logbook?

A. Right. I don't see that same sentence.

Q. Thank you. Were you aware on August 4, 1986, the date of that conference call, that a deadline had been imposed on NCHSR by the Assistant Secretary of Health to complete NCHSR assessment report by August 4; were you aware of that deadline?

A. No; I wasn't.

Q. Did you ever become aware of it?

A. I mean you tell me now that there's a deadline, but I was never much involved in that deadline. So—I mean, I may have heard hearsay about it, but it never was something vital to me.

Q. From whom might you have heard this?

A. I—you know, I may have read about it in one of the trade journals or may have heard other people talking about it.

Q. Did you ever have a discussion with Dr. Favero about this deadline?

A. Not that I recall.

Q. With Dr. Solomon?

A. Not that I recall.

Q. With Dr. Martone?

A. No.

Q. With anyone at all at CDC?

A. I really don't recall anyone ever mentioning it or talking about it specifically. But again, I wouldn't have paid that much attention to it as it was not really that significant to my work.

Q. Might there have been a mention of this deadline during that August 4 conference call?

A. There might have been.

Q. You just don't recall?

A. I don't recall it though.

Q. Are you aware that on August 15, 1986, HCFA published a final regulation reducing Medicare care reimbursement for dialysis clinics?

A. I'm aware of that.

Q. When did you become aware or that?

A. I believe it was 1 week ago.

Q. From whom did you learn it?

A. From you.

Q. You did not know about this prior to our conversation?

A. I had heard rumor about that only before that, you know, people mentioning that it might be a possibility. But the only one who I heard it stated as a fact was from you then.

Q. Rumor within the CDC?

A. Within the CDC and at the dialysis clinics.

Q. Dialysis clinics? When were you last at a dialysis clinic?

A. I don't know, within the last 2 weeks.

Q. Was that one of the four that you inspected initially?

A. One of the four investigations, yes, I did one recently.

Q. Would you identify for us the name of the clinic that you inspected 2 weeks ago?

A. It was——

Q. Would you like to refer to your logbooks?

A. Yes, I could give you the name of that if you wanted. It was in Culver City, CA, Culver City dialysis services.

Q. And just exactly what did that visit involve?

A. That was an investigation of pyrogenic reactions in hemodialysis patients who were on high flux dialysis in which dialyzers were reused.

Q. And what was the chemical, disinfectant?

A. The chemical used—well, there were—they used formaldehyde for a period and then they used renalin. And then they had these reactions and then they went back to formaldehyde. And we reviewed the three cases—the several cases that had occurred, I think it was three.

And then we did some efforts at case assessment during the formaldehyde periods and found no reactions had occurred during the formaldehyde periods. So it was our impression that it occurred during renalin reprocessing and on one dialyzer type.

Q. The chemical was renalin?

A. Yes; Renal Systems, Inc.

Q. Spelled R-E-N-A-L-I-N?

A. Yes.

Q. Wasn't this the chemical involved in the clinics in Georgia?

A. Yes.

Q. So to date you've investigated the Inglewood, CA, clinic?

A. Yes.

Q. You investigated a clinic in Dallas, TX?

A. Yes.

Q. Did you investigate the clinics in Georgia?

A. Two clinics in Georgia.

Q. That's four. And then 2 weeks ago you went back. So you've done five, not four?

A. Well, I said four investigations. It was five clinics. The two centers in Georgia we conducted as one investigation.

Q. But it involved two clinics?

A. It involved two clinics.

Q. So we're talking about five clinics, not four?

A. Four investigations, five clinics.

Q. We're talking about investigations of five clinics?

A. Yes, yes. I call them four investigations because we number each investigation. And the one investigation in Georgia involved two clinics, but it was considered one investigation.

Q. Do you know of an infection outbreak in Daytona Beach?

A. Yes; I had heard of several cases of infection there. And we talked with some of the people there at the time.

Q. Does CDC intend to visit Daytona Beach?

Mr. RISEBERG. Could be take a short recess?

Mr. MICHIE. We're in recess for a few minutes.

The WITNESS. Do you want me to answer that question before we recess?

Mr. RISEBERG. Hold, hold.

The WITNESS. OK.

[Short recess.]

Mr. MICHIE. Back on the record.

By Mr. MICHIE.

Q. Dr. Murphy, you were about to answer the question.

A. Yes; you asked about whether CDC was going to participate in an investigation. We did consider it at one time. As of right now I don't think there's any strong interest in going to look there.

Q. Why is that?

A. Well, it was a small number of cases——

Q. How many?

A. I don't remember exactly. Two or three.

Q. Wasn't that the case in the Georgia clinics?

A. It was, it was. And I felt the same way about the Georgia clinic, that there wasn't enough information there to make much of a conclusion. And I feel the same way about Daytona.

Q. Well, why did you go to Georgia?

A. Because, there was a tremendous amount of interest, and even pressure I'd say, to conduct investigations because of the amount of interest in this subject area.

Q. Did you find in the majority of your five investigations, of the five clinics, did you find that the number of reuses, frequency, the number of reuses was higher in patients with infections than in patients without infections?

A. We found that in two of the cases, two of the clinics.

Q. In two of the clinics. Did you find this in the Dallas clinic?

A. Let me see. I'm sorry, we found it in two definitely. We were not able to show that statistically in the two Georgia clinics. And——

Q. What about Dallas?

A. In Dallas we showed it, yes.

Q. What about Inglewood?

A. Dallas and Inglewood.

Q. What about Culver City?

A. In Culver City it was a small number of cases. The mean was higher, but it was not significant statistically. So we can't say yes it was higher.

Q. For sure?

A. It was a trend toward higherness, but not a statistically significant difference. So only in two clinics we showed in multiple analyses that it was higher in those patients that became infected.

Q. Two of the three—two of the five clinics that you inspected and possibly in a third? Isn't that correct, possibly in a third?

A. You can't say possibly. What I mean by statistically significant is you can say it's unlikely to be by chance.

Q. But possibly?

A. Well, possibly, and it's possible to have occurred only by chance. So, yes, possibly.

Q. Well, those are pretty high statistics; aren't they? Of course, realizing the fact that five clinics isn't a big enough sample in order to try to extrapolate statistics for the entire Nation, but nonetheless, in this particular sampling of five clinics, you found that at least in two and possibly three that this was the case, that the number of reuses, that the number of reuses in patients that reuse more than others, these patients had a higher rate of infection; isn't that correct?

A. Right.

Q. Does this indicate to you that the CDC should go forward with that epidemic investigation that was recommended, that was talked about, in that July 8 memo we discussed earlier?

A. Go forward with the investigation? I'm not sure which one you're talking about.

Q. Well, the July 8 memo, the July 8 memo, the draft memo——

A. Yes.

Q. Didn't you propose in there such an investigation, epidemic investigation?

A. Yes—well, I think it proposes some sort of study.

Q. Well, what's the title of the memo, Dr. Murphy? What does it say?

A. Epidemic aid investigation of bacteremia associated with reuse of disposable hemodialyzers.

Q. Isn't that what this memo is about?

A. Yes.

Q. And were you not proposing, you and—if this memo had gone forward, weren't you proposing that such an investigation be launched?

A. Yes.

Q. Why?

A. Because we were interested in finding out the risk factors associated with this kind of infection and means of preventing them.

Q. Weren't you also concerned in addition to being interested?

A. Yes. Interested and concerned.

Q. Concerned for whom?

A. For the patients.

Q. Are you aware that HCFA relies heavily upon NCHSR for advice and guidance on health technology assessment in administering health care programs? Are you aware of that?

A. Somewhat; I mean I'm not intimately familiar with the workings of HCFA, but that's the impression that I got.

Q. From whom did you get this impression?

A. Not specifically through my regular CDC role, I mean my readings in the newspaper, and things like that.

Q. You don't—are you saying that you don't recall any discussion with anyone at CDC or any other PHS agency pertaining to HCFA's reliance, heavy reliance, upon NCHSR?

A. I don't remember any specific conversations that, you know, address that issue.

Q. Are you also aware that HCFA relied on the NCHSR August 6, 1986 assessment report in determining whether to go forward on August 15 with dialysis reimbursement reduction?

A. I wasn't really aware of that.

Q. When you say you weren't really aware of that, what do you mean by that?

A. Well, I mean you hinted at it last week. I kind of pieced it together somewhat. But it's never been a real interest of mine or some—or duty of mine at CDC or anything that's come up within my duties.

Mr. RISEBERG. Your main source is Mr. Michie earlier?

The WITNESS. Mr. Michie and something I've read in the newspaper.

Mr. MICHIE. I'd like to share with you now a one-page memo dated August 11, 1986. This document is a addressed to Dr. Roper, HCFA Administrator, from Dr. Windom, Assistant Secretary for Health.

Did you see this memo prior to your appearance here today? And take you time looking at it. This memo has to do with transmittal of the Assessment report to HCFA from the Public Health Service, Dr. Windom.

A. OK. I've read it.

Q. Do you recall having seen this memo prior to coming here today?

A. No; not really. I think that it might be in the—that transcript that you gave me last week. But I don't remember reading it in detail before.

Q. What transcript did I give you?

A. You gave me that green book last week.

Q. That was the hearing record from March 6?

A. Yes; So that couldn't have been in there. No; I've never seen it before.

Q. Do you recall my having read to you over the telephone on August 19 certain passages from this memo?

A. Yes; I do.

Q. The first of those passages that I read to you over the phone reads as follows, quote: "The findings to date indicate that when physicians and facilities exercise appropriate quality control, patient outcomes appear to be no different in facilities that reuse dialyzers than for those facilities where single use is the normal operative mode."

Based upon your experience, Dr. Murphy, and in light of the inadequacy of the existing data base on patient outcomes associated with reprocessing and reuse, do you agree with this statement?

A. Well, I think that this statement is based on the results of the HCFA survey.

Q. But I don't speak of the HCFA survey. We've established earlier in this deposition that the data base is inadequate.

A. Right.

Q. It's so inadequate that you can't even determine whether it ought to be promoted, tolerated, or prohibited. So I ask the question in that context as well as based upon your experience. Do you agree with this statement?

A. I think it's a reasonable statement. It says the findings to date indicate, and, therefore, the statement is based upon existing data. And I think as far as existing data goes, it's a reasonable statement.

Q. Is it an accurate statement?

A. Yes; I think to some extent.

Q. Is it one that gives the necessary qualifications?

A. Yes.

Q. It does? Where do you see the qualifications about the data?

A. It says "the findings to date indicate."

Q. Do your findings to date indicate this?

A. That's what the survey shows.

Q. The survey you said a moment ago has not been tested, has not been assessed?

A. Right.

Q. So how then——

A. It still indicates that. It's a finding and it indicates that. And that's what this says.

Q. What you're saying is that a data base that has not been tested and not been assessed and that was even stated so in a letter in answer to Dr. Carter, that that supports this statement?

A. I think so. It—now, I mean it supports that statement. The—you know, the validity of that study is in question, but there's no reason to assume that the study is wrong.

Q. Is there reason to assume that it's right? If you shouldn't asume that it's wrong, then why should you assume that it's right, Dr. Murphy?

A. Well, basing his statement on findings that have been done, you know——

Q. If the validity, Dr. Murphy, if the validity of the survey is unknown, if we don't know if it's good or accurate or if it isn't then does that not affect the validity of this statement?

A. Well, it does, yes.

Q. Should not this statement have qualified this and instead informed Dr. Roper that although the data base is inadequate, inadequate to the point that we don't dare promote, we don't dare tolerate, or even dare do anything else with regard to reuse, shouldn't it have given those qualifications? Nevetheless, Dr. Roper, it appears that patient outcomes are no different, I mean would that have made any sense, Dr. Murphy?

A. I'm not sure exactly what your question is there.

Q. My question to you, Dr. Murphy, is is this a valid statement in light of the fact that it relies upon an unvalid data base and obviously does not rely upon the findings in your own investigations over the past year?

A. Well, it's a statement that relies on the data base that's unvalidated, yes.

Q. And so do you believe that this statement contains the necessary qualifications in order to adequately inform Dr. Roper of what in fact there is in the way of data and in the way of proof, for anyone to state that patient outcomes appear to be no different in facilities that reuse dialyzers than for those that don't?

A. I don't think it's an in-depth discussion of the data that's there.

Q. Indeed you don't think it's an in-depth discussion. If you had been writing a sentence for this particular passage, how would you have put it, Dr. Murphy? If Dr. Roper had called you on the telephone and had asked you, Dr. Murphy, I would really like to know, there's a lot of confusion abroad in this Department, we're getting all kinds of different answers from people, Dr. Murphy, would you please tell me what are your feelings about patient outcomes, what would you tell him?

A. I would say that as far as the data shows to date, as far as we know, there's no significant difference between rates of infections in patients in whom dialyzers are reused and in patients in whom dialyzers are used once.

Q. But, wouldn't you also add a but?

A. I would say also that the studies have not been extensive, there have not been large clinical trials, and certainly further studies could address that issue.

Q. And would you also tell him that there have been no control clinical studies?

A. Well, I do know of one controlled clinical study that has been done. I found out about it recently. It's a small study. But that was the result of it. It was done in Germany I believe. It was a very small study, low reuse numbers. But it was a comparison, clinical comparison of single use dialyzers and reused dialyzers. And it showed the same thing, that there was no significant differences in rates of infection between the two groups.

Q. Is that study in Germany adequate enough to provide the answers that you believe need to be obtained?

A. No.

Q. Would you also have informed Dr. Roper that the data base with regard to the joint CDC HCFA national survey, annual survey, that there were no national statistics? Would you have also informed him of that?

A. If he had asked me about the national statistics on infection rates, I would inform him about that survey.

Q. Would you also have informed him that the survey itself does not ask specific questions with regard to actual incidence of infection in these clinics, would you have told him that also?

A. I'm not exactly sure of the wording of the question from the survey.

Q. Well, about an hour or more ago, Dr. Murphy, you stated that the statement that I made with regard to that was accurate.

A. Yes.

Q. Do you recall that?

A. Which statement did you make?

Q. Let me go over it for you. The question was is it true, Dr. Murphy, that because CDC has not included in their surveillance activity any specific questions dealing with increased rates of bacteremia associated with reuse, there is no data covering this potential hazard on a national basis? Your answer was yes.

A. Yes.

Q. Do you still hold to that answer?

A. Yes.

Q. Would you not have told Dr. Roper this had you been writing this memo?

A. Had he asked me that question, I would answer the same question—with the same answer.

Q. You would not have volunteered this piece of information to him in light of——

A. It would not be my role, my job, to inform him of this. And I could not hypothesize as to what I would say if I were Assistant Secretary of Health.

Mr. Riseberg. This is completely speculative as to what he might say in these contexts. He hasn't given it any thought in the context of how he would respond to these hypothetical questions that you're making up as you go along.

By Mr. Michie.

Q. Nonetheless, Dr. Murphy, the way this particular sentence is presented, the findings to date indicate that when physicians and facilities exercise appropriate quality control, patient outcomes appear to be no different in facilities that reuse dialyzers than for those that don't? I'll ask you the question again: do you feel that this adequately informed Dr. Roper, first of all, about the deficient data base, did it inform him of that?

A. I never said the data base was deficient.

Q. All right. Inadequate?

A. Unvalidated.

Q. Invalidated, whichever you prefer?

A. Unvalidated, not invalidated.

Q. Whatever you prefer, any of the above?

A. I don't think that that sentence informs him that data is unvalidated.

Q. Based on your inadequate or unvalidated data base on patient outcome with reprocessing and reuse, do you agree with this statement, yes or no?

A. I think based upon the findings to date this is a reasonable statement, reasonable summary of what's known about reuse.

Q. Did you or to your knowledge did anyone else at CDC provide NCHSR or the Assistant Secretary for Health with anything that would have led Dr. Windom to reach this conclusion?

A. I don't know who provided Dr. Windom information with regard to this. I mean he has access to all of the information at CDC I'm sure.

Q. But you didn't personally?

A. He didn't call me in to talk to me about it, no.

Q. I want to refer you now to the findings and conclusions of the assessment report. And I'd like you to look in there to see anywhere if you can find in the findings and conclusions a statement resembling the one I read from Dr. Windom's August 11 memo, if you can find anything in there resembling that please.

We'll go into recess for 5 minutes.

[Short recess.]

Mr. MICHIE. Let's go back on the record.

By Mr. MICHIE.

Q. After having had a chance to review the findings and conclusions, do you find anywhere in there the statement, the one that I read from Dr. Windom's memo?

A. No, I don't find it anywhere in there.

Q. Can you explain or do you have any idea then as to how this statement got into that memo?

A. I don't know.

Q. Wouldn't you suppose, wouldn't you assume—I don't want to put words in your mouth—if a statement were in the cover memo that it would also be contained in the report itself? Doesn't that sound logical?

A. I don't know. It depends on the purpose of the cover memo.

Q. Right, at the very least to be accurate, you know, in so far as what's in the report is concerned. That's what I'm trying to get at.

A. Yes.

Q. A second passage from Dr. Windom's August 11 memo reads as follows—if you will get the memo. Do you have it there?

A. Which one, the August——

Q. I'm going to read it. "Absence of reported increases in the morbidity or mortality given increased practice of reuse suggests that virtually all facilities are following adequate procedures."

Again, Dr. Murphy, based on your experience and in light of the inadquacy of the existing data base, is this is a true and accurate statement in your opinion?

A. I don't think that it's an accurate statement.

Q. Why don't you think so?

A. Because I don't think that—let me see. Because I don't think the absence of reports of increases in morbidity or mortality necessarily mean that all facilities are following adequate procedures.

Q. As a matter of fact, is it not your belief that there is a need for study, controlled clinical study, to determine morbidity and mortality among this group of patients; is that not the case?

A. Yes, my opinion.

Q. Is that the opinion of Dr. Solomon?

A. I believe so.

Q. Is that the opinion of Dr. Martone?

Mr. RISEBERG. Have you discussed this specific issues——

The WITNESS. I've discussed them with Dr. Solomon, not much with Dr. Martone.

By Mr. MICHIE.

Q. Did you, or to your knowledge did anyone else at NCHSR, provide anything at all that would have led him to put this statement in his memo?

A. To put what statement in his memo?

Q. The one you just read.

A. I imagine that was based on the CDC information.

Q. Is that an incorrect statement?

A. The survey?

Q. That inaccurate statement?

A. I imagine that statement was based upon the survey. Because it says the absence of reported increase in morbidity and mortality, and that's a reference to the HCFA CDC survey.

Q. Nonetheless, you believe the statement to be inaccurate; is that correct?

A. [Witness nods in the affirmative.]

Q. I'd like to share with you now a memo dated May 8, 1986, to Dr. James Mason, director of CDC, from Drs. Solomon, Hughes, and Favero of CDC. This memo pertains to the infection outbreak among patients at a California dialysis clinic, beginning in early April of this year.

Have you seen this memo prior to your appearance?

A. Yes, I have seen this before.

Q. You have. Can you explain why the memo is labeled, quote in all caps, "FOR ADMINISTRATIVE USE, LIMITED DISTRIBUTIONS, NOT FOR PUBLICATION"?

A. I'm not exactly sure. But that's all of the memos in this—of this, we call this an EPI-1 document, all are labeled like that.

Q. All are labeled that way?

A. Yes.

Q. Let me share with you now an undated two-page document labeled "Oral Report, Tuesday a.m. Conference, Intradialytic Bactermia, Los Angeles."

A. Yes.

Q. Did you generate this report?

A. Right.

Q. When and for whom did you generate it?

A. I gave this as a brief update at a Tuesday morning conference at CDC. I don't recall the exact date. It was about the last week or so in May.

Q. Last week in May?

A. Yes.

Q. Was this a telephone conference or was it a meeting?

A. This is our regular Tuesday morning conferences at which people would report on all ongoing investigations at CDC. It is a telephone conference in that people listen in who are CDC personnel assigned to the State health departments.

Q. On the last page of this document is a statement, quote: "We conclude that this cluster"—and I'm going to paraphrase here, and tell me if I'm taking anything out of context—we conclude that this cluster [of infections] is etiologically related to reuse of hemodialyzer membranes. Cellulose acetate dialysis membranes, and a higher number of dialyzer uses appear to be risk factors for bacteremia.

A. That's what it says.

Q. Are you still of the belief that such infections can at least in part be attributed to a higher number of dialyzer reuses?

A. If I was to say this again, I would add one thing, and that is "is etiologically related to reuse of hemodialyzer membranes with

Alcide brand Renew-D" because we don't know if this information is valid with the use of other disinfectants.

Q. But you don't know that it isn't?

A. No.

Q. When did CDC decide that your findings from the several inspections you conducted at dialysis clinics in May and June of this year warranted an alert to the public in the CDC's morbidity and mortality weekly report, MMWR?

A. When did we decide that?

Q. Right.

A. Well, it was in the middle of that investigation, near the end of that investigation as we started to get the results, we knew right away we wanted to print an MMWR article.

Q. Which investigation was that?

A. That was the end of the dialysis investigation, one you said?

Q. I didn't say.

A. At the end of the dialysis investigation which was conducted in June, June I think 11 through 19.

Q. Who was it that made the decision for the MMWR article, who was it said we should publish an article?

A. I'd say it was myself and Steve Solomon and Bill Martone.

Q. Did you assist in the drafting or review of the article?

A. Yes, I did.

Q. To what extent?

A. Every word.

Q. Did during the drafting of this article CDC collaborate with FDA and NCHSR in preparation of the article?

A. Yes.

Q. With whom at FDA did you collaborate?

A. I spoke with several people. I don't know that I remember all their names. But I spoke with Marie Reid. And I believe that's in the Center for Devices.

Q. Dr. Villarroel?

A. I don't recall speaking personally with Dr. Villarroel. But I know that Dr. Solomon was in communication with him. And Dr. Solomon did also go to Washington and meet with some FDA representatives there.

Q. Do you recall when?

A. That was somewhere in the range of the 20th to the 25th of June. It was right after the investigation. It may have been the 20th or 21st, right after I came back from Dallas.

Q. And what was the date on which you returned from Dallas?

A. I think it was the 19th.

Q. The 19th of June?

A. As far as I remember, yes.

Q. Did you have occasion to speak with a Mr. Eccleston at FDA?

A. Eccleston, I don't recall speaking to him, no.

Q. Eccleston?

A. No.

Q. Dr. Welford?

A. No; I don't recall speaking with him.

Q. Mr. Benson?

A. No.

Q. Mr. Villforth?

A. I have spoken with Mr. Villforth but I don't recall speaking—I didn't talk to him about this, about—at that time.

Q. When did you speak with Mr. Villforth?

A. I met him in Washington about 2 weeks ago when I was up here.

Q. Was this at a meeting?

A. It was at a meeting up here, Department of Health and Human Services meeting.

Q. What about NCHSR, with whom have you discussed—or had you discussed the article at NCHSR?

A. I spoke with Mr. Erlichman once in addition to that one conference call that we had spoken of before. And a Dr. Handlesman I believe also at NCHSR.

Q. What about Dr. Carter?

A. Other than that one conference call I don't ever recall speaking with Dr. Carter.

Q. Dr. Marshall?

A. Dr. Marshall we spoke with in writing that article we spoke with Dr. Marshall.

Q. You did?

A. Yes.

Q. On how many occasions?

A. I think it was like the day or two before the article I think we spoke with him at least one phone call, maybe two phone calls. But I remember distinctly one phone call.

Q. And tell us what was that phone call about.

A. It was about the wording of the article.

Q. The wording?

A. Yes.

Q. Did they find something wrong with it?

A. They had suggestions about, you know, the wording, some editorial type comments. Mr. Marshall—Dr. Marshall did.

Q. Let's refer back now the photocopies of the log entries that we shared with you earlier, Dr. Solomon's log entries.

A. Yes, yes.

Q. And if you would turn to page 9, the numbers are at the bottom of each page. We took the liberty of numbering the pages.

A. Yes.

Q. Under the date of June 10, 1986, Is the entry, quote: "Spoke with Marie Reid in a.m. re: Dallas, Texas and plans for MMWR."

A. Yes.

Q. Now, at that time during June—on June 10 you were in Dallas; were you not?

A. No; I think I went the 11th.

Q. You went on the 11th. Were you aware of this conversation between Dr. Solomon and Marie Reid?

A. Well, I didn't realize he was already planning the MMWR article at that point, but I guess he was.

Mr. RISEBERG. Have we established that these are Dr. Solomon's notes?

Mr. MICHIE. Yes, he did; earlier he did establish that.

Mr. RISEBERG. That one part. But you did, in fact, get them from Dr. Solomon?

Mr. MICHIE. They were sent to us from CDC.

The WITNESS. I'm sure that these are his notes.

Mr. RISEBERG. OK.

The WITNESS. I know that he was in communication with Marie Reid all throughout this.

By Mr. MICHIE.

Q. But you didn't know it had happened that early?

A. Well, I knew he was in communication with her at that time. I didn't know that he had discussed plans of an MMWR article with her at that point in time.

Q. You thought it was later?

A. Well, you know, he obviously foresaw the article before I was thinking about it.

Q. Because you hadn't—you were just on your way to Dallas?

A. Yes. But we knew something was going on in there. And we knew even in Los Angeles we would have liked to publish an article but we didn't have enough documentation of the problems.

Q. Are you aware that FDA's policy has been to recommend against controlled clinical trials to determine the safety and efficacy of reprocessing and reuse of dialysis disposables? Are you aware of that?

A. No; I'm not.

Q. Are you aware that Dr. John Marshall, director of NCHSR, has taken the same position during his testimony before this committee on March 6 of this year and thereafter? Were you aware of that?

A. He took the position of?

Q. That controlled clinical study was not necessary? Are you aware of that?

A. I'm aware of that.

Q. Can you explain why Dr. Murphy, in light of the paucity of safety data on the efficacy of reuse, why would Dr. Marshall as well as the management of FDA, why would they take this position at this committee's March 6 hearing, that position being against these controlled clinical studies?

A. The only thing I can imagine is that they're against it because of the cost entailed.

Q. Let me share with you now a note dated June 25, 1986, to FDA Commissioner Young from James Benson.

Mr. RISEBERG. You said the 25th.

Mr. MICHIE. June 25, 1986 to FDA Commissioner Young from James Benson who is Deputy Director of the FDA Center for Devices and Radiological Health.

By way of background, the memo concerns the CDC's MMWR article on infection outbreaks in clinics reusing dialysis devices.

Down in the third paragraph of the note, Dr. Murphy, it reads, quote:

> We have been told that CDC plans to release the MMWR article this Friday.

And then skipping on to the next sentence:

> Our staff have been in contact with both the authors of the article and reviewing officials to suggest some changes to bring it in line with the statements about dialysis reuse made by Dr. John Marshall and John Villforth at the Congressional hearings on this subject this past March.

Had you seen this memo prior to coming here today?

A. I've never seen this memo before.

Q. What to your knowledge was the extent of CDC's collaboration with FDA and NCHSR concerning the content of the MMWR article? A moment ago you did state that there was some discussion about the content, wording.

A. Yes.

Q. To what extent was that?

A. The bulk of it was written by CDC, and there were some editorial and content changes made, you know, during the editing process with both with FDA input and some input from Dr. Marshall near the very end.

Q. Now, which of the two agencies would you say offered the most input? Was it FDA or NCHSR?

A. Well, FDA, we worked with FDA on the investigation, and all the way along they had input. Dr. Marshall's input was only toward the very end of the writing process.

Q. During these discussions about content of the article, would you say that FDA was concerned with the accuracy of the article or with what was included in the article even if it was accurate as well as pertinent to the dialysis clinics?

A. I think that FDA was concerned with the accuracy of the article.

Q. Was it also concerned with what went into the article even if it was accurate?

A. I think, yes; it was also concerned with what went into the article.

Q. Why would it be concerned about what went into the article even though it was accurate? Why would it be concerned about that?

A. I'm not aware of, you know, their motivations of things. I don't know why—I mean I understand why they'd be concerned about its accuracy since they participated in it and were listed as authors.

Q. Of course. But why then would they be concerned about statements being put into that article that were accurate?

A. I'm not sure why they would be concerned.

Q. But they were; were they not?

A. I think they were; yes.

Q. Could you give me an example or two?

A. I really don't have exact memory of what exact changes they, you know, they had suggested.

Q. We have something here that you can refer to. To the best of your recollection, how many drafts were there of this morbidity and mortality weekly report?

A. At least seven or eight.

Q. At least seven or eight?

A. Yes. I mean seven or eight written drafts that might have been circulated. It's changed you know, 100 times. I mean it's a constant editing process. I myself read it and made changes in it a lot. And other people read it and made changes a lot. So I'd say that there was at least seven or eight drafts that were circulated to various people for approval or comments.

Q. Let me—I'd like to share with you those drafts that we have in our possession that were provided to us by CDC. We have a set of four drafts, a copy of which you have before you now, and then also attached to that is the final version that was published in the MMWR.

A. OK.

Q. This article, is entitled "Bacteremia Associated with Reuse of Disposable Hollow-Fiber Hemodialyzers." Do any of these drafts look familiar, Dr. Murphy?

A. Yes; they all look familiar.

Q. If you would turn now to page 3 of draft No. 1. And we are assuming that this was draft No. 1 insofar as what CDC sent to FDA. If you will notice, the cover page, the facsimile transmission page, bears the date—would you read the date there.

A. June 23, 1986.

Q. That is one of the earlier drafts; is it not?

A. I believe so, yes. Because I only got back from Dallas on the 19th, so this—you know, this was early on.

Q. If you'd turn to page 3 of draft 1 then, we'll call it draft 1 for the sake of the record.

A. OK.

Q. The editorial note in this draft contains the following passage:

> There are, however, no controlled clinical studies validating the safety or assessing the risk to patients of the practice of the reuse of disposable hemodialyzers, nor are there controlled clinical studies comparing the morbidity and mortality of patients being dialyzed with new dialyzers with that of patients being dialyzed with reprocessed single-use only dialyzers.

Now, was this passage at that time, and isn't it still today, a true and accurate piece of information?

A. Well, as I said, I have recently found out of one small controlled study from Germany. But——

Q. For all practical purposes would that have changed this?

A. No; That's basically a true statement.

Q. Now, was this statement dropped from the MMWR article at the request and urging of anyone at FDA or NCHSR?

A. Well, I believe it was dropped from the article. I mean it was not published—it was not in the final one.

Q. That's correct, it was dropped. And it was dropped—it was not included in the draft No. 2 that we have?

A. Yes.

Q. Was that one of the statements that was not to the liking of FDA?

A. I think that they may have participated in the fact that we dropped that line. I think that that's true.

Q. Do you recall FOA explaining to you why they wanted that dropped?

A. No.

Q. On that same page of the draft No. 1, the draft that we're calling No. 1, there's a statement:

> There are, however, no federal standards for ensuring the functional or microbiologic quality of single use only hemodialyzers reprocessed in dialysis clinics.

Do you see that there?

A. Yes.

Q. Wasn't this statement at the time of that writing, and isn't it still today a true and accurate statement?

A. Yes, it is.

Q. Was this statement dropped from the MMWR article at the request of the FDA?

A. I believe that the word "federal" was removed there. Let me see.

Q. I think you're correct in draft No. 4, the world "federal" was taken out. But if you will examine the final publication, I think the entire sentence was removed; was it not?

A. Well, we rearranged that whole paragraph, and I think—let me look at it. Is there a copy of the final—here's the final. Yes, it was removed.

Q. Now, do you recall whether or not FDA asked you to remove that particular passage?

A. I think that FDA was involved in the decision to remove that statement.

Q. Was NCHSR also involved in that decision?

A. I think it maybe was removed before we even—before Dr. Marshall was involved. But I'm not sure.

Q. Do you recall who at FDA asked you to remove that statement?

A. No.

Q. Finally the last sentence of the editorial note on page 3 of the first draft states:

> Until further information is available, CDC recommends that providers of dialysis services who reuse single-use only dialyzers review their practices and experiences and assess whether alternatives to one time use of dialyzers are appropriate and optimally beneficial to patients.

Was this recommendation dropped from the article at the request of anyone at FDA?

A. I don't know that there was any FDA input into that. There may have been.

Q. Do you—I'm sorry, go ahead.

A. This was more of a CDC based recommendation I think.

Q. And did you agree with that recommendation?

A. Well, the——

Q. Did you not write that?

A. Yes, I did. And the wording is not much changed from the final version, which CDC recommends that providers of hemodialysis services review their experience and assess the clinical safety of their hemodialysis practices. I think it does——

Q. But that does not make the differentiation that's made in here.

A. Right, it doesn't.

Q. In other words, it doesn't address the practice of reuse, whether or not they ought to see if they ought to determine whether they ought to quit reusing. And that's the point you make in the first draft; is it not?

A. Right.

Q. Now, after discussing this with me for a moment, I'll ask you again, do you think FDA—was it FDA who requested that you change, that you remove, or that you edit that statement into the version that was published? Was there a discussion about the wording?

A. I actually think that the wording on that was changed more within CDC.

Q. Now, if you will turn to the actual publication of the article, the final version——

A. Yes.

Q. The last sentence of the editorial note which reads as follows: Additional studies of the functional and microbiological quality of reprocessed hemodialyzers, as well as the factors affecting their clinical safety, are needed to formulate guidelines."

A. Yes.

Q. What kind of additional studies do you believe should be conducted in order to determine the safety and efficacy of reuse? What type studies were you referring to?

A. Well, we referred to the possibility of clinical studies, the possibility of studies that would be more a registry based studies, and certainly laboratory based studies.

Q. Do you recall having a conversation with me over the telephone about this very article and about this point?

A. Yes.

Q. Do you recall me having asked you what you meant by that and——

A. Yes. You asked me for my opinion on what I felt needed to be done.

Q. And do you recall having stated to me that when you wrote that passage you meant it to mean controlled clinical study? Do you recall that?

A. I said that in my opinion that would be the best study to be done.

Q. And did you not tell me that that's what you meant when you wrote that?

A. Well, many people wrote this. And you asked me for my opinion. I said, yes, I think that controlled clinical studies should be done. But I'm not the only one who wrote this article.

Q. And then do you recall me asking you, well, if that's what you meant, Dr. Murphy, why didn't you say so? Do you remember that?

A. Yes.

Q. And what was your answer?

A. I don't recall exactly what was my answer.

Q. Could your answer possibly have been that what your opinions or wishes were didn't necessarily reflect the policy of CDC, wasn't that your answer?

A. Yes, I probably said that. And I'm saying the same thing here, because this article is a result of many people's opinions and beliefs of which I'm, you know, low on the totem pole.

Q. Did anyone at CDC or did anyone at FDA or anywhere else in the public health system advise, instruct, or suggest to you that the words controlled clinical study not be used in this article?

A. I'm not sure if they were in earlier drafts.

Q. There was, was there not, the comment in draft No. 1 that there had been no controlled clinical studies on this particular issue as well as morbidity and mortality?

A. I know that we discussed the possibility of putting controlled clinical trials in there. But we decided not to put in there because we did prepare this in a hurry, trying to get it to press rapidly, and we thought it was more important to get the article out than to make a decision at that time as to what type of studies needed to be done. And that's why we said additional studies and didn't specify exactly what type of studies needed to be done.

Q. Does Dr. Solomon share your opinion that if studies are to be done that they should be controlled clinical studies?

Mr. RISEBERG. Have you spoken with Dr. Solomon specifically about this position?

The WITNESS. I've spoken with Dr. Solomon. I think he believes—he would like to see clinical studies done too.

By Mr. MICHIE:

Q. For what purpose?

A. Because that would be the optimal way of assessing whether or not there is an increased risk associated with reuse or single time use. Because there's certainly a possibility that single use is not better or single use may be worse because of the first use syndrome.

Q. And in whose interest would you think if it would be for these controlled clinical studies to be performed—primarily in whose interest?

A. Well, it would be in the interest of the patients that we could optimize care, and it would be in the interest of ourselves and the center—that is, dialysis centers—so that they would have a better knowledge base to base their information on—base their decisions on and base their protocols.

Q. To your knowledge has the CDC decided to improve its data base in some way with regard to the incidence of infection in these clinics, and if so what is the CDC considering in that regard at this time?

A. I don't know that there's been any, you know, consensus or decision to improve the data base. I know there has recently been established a Department task force to address the issue and make decisions as to how better information can be gathered, better data, and directions of research.

Q. At least within the CDC through, hasn't there been a consensus for some time that this data base, this inadequate, this unvalidated data base, contains no specific question with regard to the incidence of infection in these clinics, hasn't the consensus been within CDC that there indeed is a need to improve it?

A. I don't know that its a consensus. I mean I feel there's a need to improve it.

Q. Does Dr. Solomon believe——

A. I think Dr. Solomon would agree with me in that respect.

Q. What about Dr. Martone?

A. I haven't really discussed that all that much with Dr. Martone. He hasn't been all that involved with dialysis per se.

Q. Do you think it's time that somebody did discuss it with Dr. Martone?

A. Well, I'm sure some people have discussed it with Dr. Martone.

Q. But you're not privy——

A. I haven't. I have worked mostly with Dr. Solomon.

Q. Do you believe that it's wise at this time because of a need for these studies, these further studies, to encourage in any way increased reuse of disposable dialysis devices, including the dialyzer, the blood lines, transducer filter, and the dialyzer caps?

A. I'm sorry, do I think it's wise——

Q. Do you think it's wise to encourage increased reuse? We've established there's a need for further studies?

A. We know there's a need for further studies.

Q. Do you think it's wise at this time while we're still trying to find determine what to study that someone encourage an increase in reuse of these disposables?

Mr. RISEBERG. Has it been established that anyone's encouraging it.

The WITNESS. I personally don't think that would be a wise idea.

By Mr. MICHIE.

Q. You don't think so?

A. Right.

Q. Am I correct in stating that, if there is reduction in dialysis reimbursement rates, would not the clinics that don't reuse be encouraged, if not forced, for economic reasons to begin reusing these devices?

A. I'm really not sure. I mean I don't know that much about their economic operations and things. But I suspect that cutting reimbursement would tend to make them want to reuse more.

Q. Encourage more reuse?

A. Yes.

Q. Do you think that's wise? Again, I'll put the same question to you. Do you think it's a wise decision?

A. I personally don't think it's a real wise decision.

Q. And do you base that upon your experience and knowledge having been out in the field and inspected at least five of these claims?

A. Yes.

Q. Are you aware that the FDA contracted with three States, California, Ohio, and Massachusetts, and the District of Columbia, to conduct surveys of dialysis clinics?

A. Yes.

Q. When did you become aware of this?

A. I don't know exactly when. Over the past 2 months, some time maybe—maybe in June. I think I was aware of it about the end of June, beginning of July.

Q. Have you read any of these reports?

A. I have not read them all. But I have looked at them today, some of the reports, the ones from the District of Columbia and California. I've had a chance to skim them briefly.

Q. Was this the first time you had had the opportunity to see——

A. Yes.

Q. [Continuing.] Any of these reports?

A. Yes.

Q. Are you aware that the reports of these contractors to the FDA indicate that there are many problems associated with reprocessing and reuse? Did you become aware of that in scanning these reports?

A. I scanned them today and saw that that seems to be some of the conclusions.

Q. For example, extremely poor procedures in reuse processing?

A. I don't recall that exact statement.

Q. Well, if you don't have procedures or if the reprocessor, the person reprocessing doesn't follow the procedure, wouldn't you consider that to be extremely poor process?

A. Well, I don't know. Not necessarily.

Q. Would that concern you at least?

A. I think optimal care would call for a written protocol and sticking to that protocol.

Q. What about adequate care?

A. I don't think there's any standards as to adequate care.

Q. You have a standard; don't you?

A. Yes.

Q. What about your standard for adequate care?

A. Well, then I think it would be better to have a written protocol and stick to it.

Q. From these reports that we gave you the opportunity to scan here today, did it become aware to you that there is also a serious lack of quality control in some of these things?

A. I think that was in some of the conclusions in those reports.

Q. And do these findings not agree with your experience in your visits and in your investigations of clinics out in the field in recent months?

A. That statement agrees with my impression from dialysis clinics that I've been to visit.

Q. Based on your experience out in the field, Dr. Murphy, and your findings and your investigations, do you have any concern at this time for the lack of expertise, for the lack of lack of knowledge, for the lack of qualifications, of not only the clinics, but also the reprocessors and the administrators of dialysis clinics? Do you have any concerns about these particular areas?

A. I'm not sure exactly what you mean.

Q. For example, are you concerned about whether or not the clinician, the clinician, generically speaking, has sufficient knowledge with regard to reprocessing of these devices, reprocessing which has and continues to take place on widely varied protocols? Do you feel that the clinics themselves have the necessary knowledge and expertise in order to determine first of all whether or not a protocol is adequate and whether in fact it does protect the patient in general?

A. I'm concerned about that.

Q. Why are you concerned about that?

A. I'm concerned because I think some of the clinicians are not intimately involved with writing those protocols or testing them, or even the day-to-day practice of them.

Q. In flushing out the devices to prepare them for reuse; is that what you mean?

A. Right, right.

Q. Do you believe that these clincis and the administrators of these clincis have the necessary expertise and knowledge in the area of toxicology in order to recognize the symptoms, the onset of symptoms, with regard to bacteremia infection? Do you have any concern about that?

A. I believe that the clinicians in those centers are capable of recognizing the symptoms of bacteremia.

Q. But suppose the clinicians aren't there?

A. Then they wouldn't be able to recognize the symptoms.

Q. And in that case, then who would be responsible for recognizing?

A. The technician, dialysis technician, would be there.

Q. And do you believe that these dialysis technicians have the training, medical training, and background in order to make these determinations in general, do you believe?

A. I would say not necessarily in all cases.

Q. Does this concern you?

A. Yes, that's a concern to me.

Q. Is there anything else that concerns you about this whole situation with regard to reuse? For example, let me ask you this: Are you concerned about the fact that there is such wide variance with regard to, if I can use the term, the recipes for reprocessing? Are you concerned about this wide variety of these recipes from one end of this country to the other, are your concerned about that?

A. I'm a little bit concerned about that.

Q. Are you concerned about such agencies as the FDA and the NCHSR relying upon the AAMI recommended practice for the guidelines in reuse and reprocessing? Are you concerned about that?

A. I don't know exactly how you mean that.

Q. Well, the FDA, both the FDA and the NCHSR, have repeatedly stated that there are guidelines in place now, formulated by AAMI. As a matter of fact FDA participated in the formulation of these guidelines.

A. Yes.

Q. The fact is these guidelines only address reprocessing—I should say attempt to address processing of dialyzers. They make no attempt to address reuse of blood lines, transducer filters, or the dialyzer caps?

A. Yes.

Q. My question to you is are you concerned about the FDA's reliance and the NCHSR's reliance upon these guidelines as being adequate? Are you concerned about that?

A. Well, if you say that these AAMI guidelines don't address reuse of——

Mr. RISEBERG. Are you familiar with the AAMI guidelines?

By Mr. MICHIE.

Q. Are you familiar with the AAMI guidelines?

A. I know that the AAMI guidelines exist.

Q. Have you read them?

A. I haven't read them in detail.

Mr. RISEBERG. Do you consider yourself able to answer questions about the AAMI guidelines?

By Mr. MICHIE.

Q. Let me put the question to you this way, Dr. Murphy: If in fact the AAMI recommended practice does not address, does not even attempt to address, the reprocessing of blood lines and these other disposables in dialysis clinics, would you feel comfortable as a clinician in relying upon these guidelines?

A. Not for issues of reuse of those items.

Q. Of those items. And are you aware of the fact that a goodly number and an increasing number of clinics, dialysis clinics in the country, are reusing these other items?

A. Yes, according to the HCFA-CDC survey.

Q. And does that concern you?

A. That's a concern to me.

Mr. MICHIE. Thank you very much, Dr. Murphy.

We want to remind you that you may—you are subject to recall in the future. A transcript of this deposition will be provided to you following its preparation. In the meantime, this desposition is in recess until further notice. Thank you.

The WITNESS. OK, thank you.

[Whereupon, at 4:02 p.m., the taking of the deposition was concluded.]

UNITED STATES OF AMERICA

Congress of the United States

To John J. Murphy, M.D., Epidemic Intelligence Service, Epidemiology Branch, Hospital Infections Program, Centers for Disease Control, U.S. Department of Health and Human Services, 1600 Clifton Rd.,N.E., Bldg. 1, Rm. 5044, Atlanta, Ga. 30333, **Greeting:**

Pursuant *to lawful authority, YOU ARE HEREBY COMMANDED to appear before the* Special *Committee on* Aging *of the Senate of the United States, on* September 8*, 19*86*, at* one *o'clock* p*.m., at their committee room* SD-G33 in the Dirksen Senate Office Building*, then and there to testify what you may know relative to the subject matters under consideration by said committee.* in sworn deposition to be conducted by committee staff.

Hereof fail not, *as you will answer your default under the pains and penalties in such cases made and provided.*

To David G. Schulke, Investigator, *to serve and return.*

Given *under my hand, by order of the committee, this* 14th *day of* August*, in the year of our Lord one thousand nine hundred and* eighty-six.

Chairman, Committee on Aging

UNITED STATES OF AMERICA

Congress of the United States

Notice of
Senate Deposition

To John J. Murphy, M.D., Epidemic Intelligence Service, Epidemiology Branch, Hospital Infections Program, Centers for Disease Control, U.S. Department of Health and Human Services, 1600 Clifton Rd.,N.E., Bldg. 1, Rm. 5044, Atlanta, Ga. 30333
, **Greeting:**

Please *take notice that at* one *o'clock* p.m., *on* September 8 , *19* 86 , at Rm. SD-G33, Dirksen Senate Office Bldg., Washington, D.C., J.F. xx Michie, D.G. Schulke & C.C. Jennings , *of the staff of the* Special *committee on* Aging *of the Senate of the United States, will take your deposition on oral examination concerning what you may know relative to the subject matters under consideration by said* Special *committee. The deposition will be taken before a notary public, or before some other officer authorized by local law to administer oaths; it will be taken pursuant to the* Special *committee's rules, a copy of which are attached.*

Given *under my hand, by authority vested in me by the* Special *committee, on* August 14 , *19* 86 .

John Heinz
JOHN HEINZ
Chairman

GPO 65-[illegible]

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

Martin Ehrlichman

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this 18th day of September, 1986, and executed the above certificate in my presence.

Jerry Ann Tipton
NOTARY PUBLIC IN AND FOR
Prince George's Co., MD

MY COMMISSION EXPIRES: July 1, 1990

WEDNESDAY, SEPTEMBER 10, 1986

Washington, DC.

Deposition of Martin Erlichman, called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 1:15 p.m., before Cathy Jardim, a notary public in and for the District of Columbia, when were present on behalf of the respective parties:

Appearances:

For the Special Committee on Aging:

James F. Michie, chief investigator.

David Schulke, investigator.

Michael Werner, counsel for investigations

Christopher Jennings, professional staff member, U.S. Senate, Special Committee on Aging, room SDG-31, Dirksen Senate Office Building, Washington, DC 20510.

For the deponent:

Richard Riseberg, Esq., general counsel, Public Health Service, Department of Health and Human Services, Washington, DC.

Mr. MICHIE. Good afternoon. My name is James Michie. I am chief investigator for the Special Committee on Aging of the U.S. Senate.

This proceeding is now reconvened, the first session having been held on August 26, 1986.

Present with me here in SDG-31 of the Dirksen Senate Office Building is committee investigator David Schulke, committee counsel Michael Werner, the notary public and stenographer, Cathy Jardim, and Martin N. Erlichman, Health Sciences Analyst, Office of Health Technology Assessment, National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service.

Mr. Erlichman is accompanied by Mr. Richard Riseberg, Chief Counsel for the Public Health Service.

On August 15, Mr. Erlichman was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging, for the purpose of being deposed by committee staff on August 26, 1986. Mr. Erlichman did appear here but declined to be sworn for testimony on the advice of Mr. Riseberg.

Following his receipt of a letter dated August 28, 1986, from Senator Heinz, chairman of this committee, in which the chairman overruled Mr. Erlichman's objections, Mr. Erlichman agreed to return here today and be sworn for deposition by committee staff. A copy of the chairman's letter of August 28, 1986, will be part of this deposition record.

Prior to being sworn in, Mr. Erlichman, I want to remind you if you knowingly provide false testimony under oath you may be subject to prosecution for perjury.

Are you ready to proceed?

The **Witness**. Yes, sir.

Mr. **Riseberg**. I would like to make a further statement for the record. To some extent this may be slightly repetitive of what was said previously.

The Department has asked me to indicate that it is volunteering to make Mr. Erlichman available in order to cooperate with the Senate Special Committee on Aging in connection with its study of issues related to dialyzer reuse and that Mr. Erlichman is participating in today's interview solely on that basis.

He has been advised by counsel for the Department that the subpoena served upon him is of doubtful legality and that the Department does not regard his appearance to be compelled by the subpoena or governed by its terms. Nevertheless, subject to this, he looks forward to answering any questions you may have.

An issue has arisen as to the authority of the notary public to administer the oath to the witnesses. While the Department continues to believe that under the standing rules of the Senate only the chair and or a member of the committee has the authority to swear in a witness, in order to cooperate with the committee and avoid further delay in getting to the committee's substantive concerns, Mr. Erlichman has agreed to take the oath in question without conceding to it any legal significance it does not otherwise have.

In so doing Mr. Erlichman has also asked me to emphasize that whether or not sworn, he would answer truthfully to the best of his knowledge.

By Mr. **Michie**.

Q. Mr. Erlichman, have you received a copy of the chairman's August 28 letter to Mr. Riseberg?

A. Yes.

Q. Just to be sure that there is no misunderstanding, we are going to give you a copy of that letter now and I want to ask you, do you understand the chairman's rulings being that the subpoena served on you a few weeks ago is in fact a valid subpoena issued by the chairman of this committee, and, second, that the oath you are about to take is in fact a valid oath which commands you to tell the truth? Do you understand that?

A. Yes.

Q. Is that your understanding?

A. Yes.

Q. I want to remind you, once again, that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury.

Are you ready to proceed?

A. Absolutely.

Mr. **Michie**. Would the notary public administer the oath to Mr. Erlichman.

Whereupon, Martin N. Erlichman was called for examination and having been first duly sworn was examined and testified as follows:

EXAMINATION BY THE CHIEF INVESTIGATOR FOR THE SPECIAL COMMITTEE ON AGING

By Mr. MICHIE.

Q. Will the witness state for the record his full name, home address and age?

A. Martin N. Erlichman, 8209 Winter Snow Court, Frederick, MD 21701. I am 39 years old.

Q. With the exception of your having received appropiate and necessary advice and counsel from the PHS Chief Counsel, Mr. Riseberg, regarding your rights as the witness in this deposition, has anyone prior to your appearance here today attempted to influence in any way your testimony in this deposition?

A. No.

Q. Have you at any time, since August 26, discussed your testimony with anyone else excepting, of course, legal counsel who represents you?

A. Could you clarify what you mean by discussing?

Q. Have you discussed your testimony that was given here on August 26 with anyone else other than your legal counsel?

A. I might have mentioned the documents that were—that you presented on that date to Dr. Carter. In that regard I might have, you know——

Q. Have you——

A. That is all.

Q. Have you had occasion since August 26 to discuss the testimony of any of the other deponents who have appeared here since?

A. Can you repeat that, please?

Q. Have you had occasion to discuss the testimony of any of the deponents who have appeared here for deposition since August 26?

A. Again, only possibly Dr. Carter, maybe Dr. Marshall in terms of, you know, regarding taking the oath. Not in any other detail.

Q. Have you discussed with Mr. Villforth, John Villfouth at the FDA, his testimony?

A. No.

Q. Have you discussed with Mr. James Benson of the FDA, his testimony?

A. No.

Q. Prior to your appearance here today you were requested to bring with you your blue folder entitled notes. Do you have that?

A. It has been provided.

Q. Along with any logs or appointment calendars, have you kept any such logs?

A. I have some notations for a visit to a dialysis center or a meeting but they were very infrequent and they might or might not have appeared.

Q. Where would those notes have appeared, in this folder or elsewhere?

A. Not in that folder. In that calendar it might note that I was supposed to be some place. It might have also appeared on a wall calendar that is ripped off each month and thrown away or in a folder with some information about the visit.

Q. Are you a Public Health Service officer?

A. Yes.

Q. For how long a time have you served and what is your rank?

A. Excuse me?

Q. For how long a time have you served and what is your rank?

A. Lieutenant commander and I will have proudly served almost 8 years in September.

Q. Briefly, if you will, give us your academic and training background, Mr. Erlichman?

A. I have an undergraduate degree in chemistry. I have a masters degree in environmental health science. I was in a Ph.D. program in toxicology and environmental hygiene at New York University, I believe completing all of the course work, if not, most.

Q. In the interest of saving the time we will refer to your agency as the NCHSR; the Office of Health Technology as OHTA, a being a component of NCHSR; the Food and Drug Administration as the FDA; the Centers for Disease Control as the CDC; the National Institutes of Health as NIH; the Public Health Service as PHS; the Health Care Financing Administration has HCFA; the U.S. Department of Health and Human Services as the Department; Arthur D. Little Inc., as ADL; and the Association for the Advancement of Medical Instrumentation as AAMI.

Could you briefly describe the function and mission of the OHTA as a component of NCHSR?

A. Primarily the Office of Health Technology Assessment receives requests from the Health Care Financing Administration to assess issues for their safety and efficacy and make recommendations to that agency as to whether they should cover or not cover the given technology or procedure. We do have other responsibilities also. That is my primary—has been the primary function.

Q. What has been your primary function?

A. Doing assessments, which is the report that is generated in response to the formal request from HCFA.

Q. Do I understand you to mean that in the conduct of these assessments, that you may very well, if not in all cases, in most cases, make recommendations to HCFA on whether or not they should take a particular action with regard to HCFA's administration of a particular health care system? Is that the case?

A. There is some difference between reimbursement and coverage. When we are asked to assess something from HCFA, which was not the case in reuse, the request did not come from HCFA——

Q. But it could have?

A. But when we do an assessment we are dealing with the area of coverage, whether or not Health Care Financing Administration should cover a given technology or new use for a technology.

Q. Could HCFA have asked you to perform the assessment that you just finished?

A. I imagine so.

Q. For how long a time have you served as a health sciences analyst at OHTA?

A. Seems like I started there yesterday. Three or four years.

Q. Would it have been 1982 or 1983?

A. 1983 sounds right. I am not exactly sure.

Q. What specifically, and briefly, if you will, tell us what your responsibilities and duties are as a health sciences analyst?

A. I think we just about covered that, that when a formal request for an assessment from the Health Care Financing Administration comes in, such as in the case of Nd YAG lasers or other issues that I have worked on, we are assigned the issue by the office director. We are asked to generate a letter in the Federal Register, a notice in the Federal Register. We are asked to contact the other PHS agencies that might have information. We attempt to contact medical specialty groups and other groups directly for their input. We are required to review the literature and synthesize that information and generate a report with that information and a recommendation, if that be the case, based on the report.

Q. Who is your immediate superior?

A. Dr. Enrique Carter.

Q. For how long a time have you served under Dr. Carter?

A. For as long as he has been office director.

Q. Was he director when you joined NCHSR?

A. No; he replaced Dr. Margolis. I would say approximately 2 years.

Q. How closely do you work with Dr. Carter in fulfilling your daily tasks and responsibilities?

A. I try to work very closely.

Q. Who is Dr. Carter's immediate superior?

A. Dr. John Marshall, the Center Director.

Q. What is the approximate number of health technology assessments in the course of which you have served as a health sciences analyst?

A. Six or seven—five or six, something like that.

Q. Five or six?

A. Five or six.

Q. Over the past 3 years?

A. Yes; you asked me for ones that are completed or in progress?

Q. No; I am asking for ones that have been completed—let's take that first. How many have you completed since you came on board in 1983?

A. About eight.

Q. How many do you have in progress?

A. A number at various stages. Two that are, I would say, are in progress.

Q. Which are those?

A. One is dual photon absorptiometry and the other is single photon absorptiometry.

Q. On average how many months does it take to conduct a health technology assessment, including the research, analysis and the drafting of a report? How long does that take on the average?

A. They vary considerably. There is a minimum amount of time because of the letters that go out and the time given for response. Dr. Carter has indicated to me that on the average they take about 9 months. We usually tell people somewhere between 6 months and 1 year. In some cases there is a lot of material to cover. In some cases there is not.

Q. So on average 9 months or more?

A. According to what I have been told from Dr. Carter.

Q. Is this how long, based on your experience, is this how long your assessments have taken?

A. At times. Sometimes they are in tandem so it is hard to put an exact timeframe, but I imagine if one looks at the time that the requests came in to the time went out, one might say so, yes.

Q. So as a rule, correct me if I am wrong, but your assignments and responsibilities do include conduct of the research, the literature search, the analysis and the drafting of the report as well?

A. Yes.

Q. In performing your assigned tasks, do you receive all instructions and assignments from Dr. Carter?

A. Yes.

Q. Have you from time to time received instructions or assignments directly from Dr. Marshall?

A. I would have to say on occasion.

Q. On occasion?

A. Most likely in this project—more likely on reuse.

Q. Is that correct?

A. Yes.

Q. What type of instruction or assignment has he given you directly? Give me a couple of examples. What has he come to you with in the way of assignment or instruction, and if you would like to refer to your notes——

A. No; they are not in my notes. The only thing that I can recall is possibly asking me if I have looked at something.

Q. If you what?

A. If I have reviewed something or he has asked me for some information where he might have been preparing a memo and asked for some general information which Dr. Carter and I would sit in with him and discuss it.

Q. Do you recall him having become directly involved with you as you conducted the assessment at any time, in other words, did he give you instruction of any kind during the course of the assessment?

A. No; By and large this was similar to my other projects where I responded to Dr. Carter.

Q. Is it the general practice of Dr. Marshall to delegate to a large degree responsibility to Dr. Carter in the conduct of health care technology assessment?

A. I am not sure I am in a position to adequately respond. I think you would be better off asking Dr. Carter.

Q. To your knowledge, based upon your observations?

A. Since Dr. Carter directs us at what we are doing, possibly.

Q. To your knowledge has Dr. Marshall on occasion ever become more closely involved in some health technology assessments than in others? Would this be the case on the assessment of safety and efficacy of reuse?

A. Probably because he was more personally involved from the beginning.

Q. He was more closely involved in this one than others? Is that a fair statement?

A. I don't know that. He may have been involved in others that I didn't work on. Transplants might be an area that Dr. Marshall might be as involved as reuse.

Q. I am asking you to speak to your experience with the assessments that you performed. Was it a case wherein he perhaps took more of an interest in this particular assessment, in the assessment of reuse than the others you have done in the past?

A. He has been involved in dual photon absorptiometry to a degree than other assessments but not as much as reuse. He wasn't a witness in a hearing for dual photon.

Q. Are you aware of the hearing this committee conducted last March 6 concerning the safety and efficacy of dialyzer reuse and are you also aware that Dr. Marshall was a principal witness for PHS?

A. I am.

Q. Were you involved at all in any way in the preparation of Dr. Marshall's testimony?

A. To some degree.

Q. To what extent?

A. In the short time that we had, we tried to collect some information to help Dr. Carter prepare testimony with Dr. Marshall.

Q. What were your assignments in this task?

A. Some of the material that we had included publications of conferences I might have had time to look through to get a feel for what had been said.

Q. From what did you receive these publications?

A. I don't recall.

Q. Did you at that time have occasion to discuss or perhaps to receive information and input from anyone at the FDA regarding Dr. Marshall's testimony?

A. Dr. Carter by and large was handling much of this—much of the material, much of the input, and he was in touch with many of the other people involved at the other agencies. I don't recall if I was. I don't think so.

Q. You don't think he spoke with anyone at FDA, CDC, NIH, or at any other agency concerned.

A. It is possible. I don't remember. We had a few days to prepare and I really don't remember. It is very possible.

Q. Do you recall the briefing books, the two large black binders that were provided to Dr. Marshall when he was informed that he would be the witness instead of Dr. Young? Do you recall those books?

A. Yes.

Q. Did you work with those books.

A. I have taken material from those, some of the studies, if that is what you mean by work with them.

Q. Did you take information from those books in order to assist in the preparation of this testimony?

A. No; the books were material that had been—put together to prepare his testimony. I am talking about months later. No; I did not take the material from that book.

Q. You didn't?

A. I don't believe so. Can you explain what you are asking?

Q. Prior to the March 6 hearing, we had previous testimony to the effect that Dr. Marshall learned only—in only a matter of days prior to that date that he was going to be the witness instead of Dr. Young, the Commissioner of the FDA, who had been invited by the committee to appear. PHS made the decision that Dr. Marshall would be the witness. Subsequently, materials contained in the briefing binder, which had originally been prepared for Dr. Young, were then passed on to Dr. Marshall and his staff. I am assuming that at that time, if you did assist in the preparation of the testimony, that you would surely have taken advantage of the material in that binder. Did you not?

A. I did not. What I thought we were doing was collecting information to put together a binder that would provide information in various areas or issues regarding reuse and so the information that I outlined was typed up by the Secretary and given to Dr. Carter and I believe that it would probably be found in the binder. I thought we put the binder together. I hadn't realized it came from FDA——

Mr. Riseberg. You don't know that?

The Witness. I don't know that.

Mr. Michie. For the record the witness is not certain whether or not we are talking about the same binder, and that is fine.

By Mr. Michie.

Q. Do you recall having worked with a binder, black binder, that was sent over from HCFA?

A. No; I realize there is one because the other day we were looking for a black binder and it was the one from HCFA. I did not write any part of the testimony.

Q. I misunderstood you then.

A. You say prepare. You can help someone prepare in many different ways. Collecting material is one way of preparing.

Q. Your role was to collect material?

A. Trying to provide data, information, for the preparation of the testimony.

Q. To your knowledge has NCHSR ever received a request from HCFA to conduct a health technology assessment on the reprocessing and reuse of dialysis devices?

A. I don't believe so.

Q. Let me share with you now a March 5, 1986, memo to Dr. Marshall, Director of NCHSR, from Dr. Donald Macdonald, the then Acting Assistant Secretary for Health. The subject is, "reuse of dialysis supplies" and it states that reuse of dialyzers, "has never been formally assessed by the PHS."

Dr. Macdonald's memo further states,

> There is a need to assess clinical and cost trade-offs between single and multiple use of dialysis filters. The importance of this issue dictates a timely analysis.

Were you assigned to work on this assessment requested by Dr. Macdonald, and if so, when were you assigned?

A. I want to read it to be sure whether I have seen it.

Q. Please. Take your time.

[Pause.]

Q. Had you seen this memo prior to your appearance here today?

A. It is possible. There are some comments that don't ring a bell. But I might have seen it. I was aware a memo did come in that resulted in the assignment of the assessment.

Q. Was anyone else at the NCHSR assigned to work on this assessment besides you and Dr. Carter? Was there anyone else involved?

A. Well, nobody, as far as I know—no one else was assigned.

Q. Who was in charge of this assessment, realistically speaking, was it Dr. Carter or was it Dr. Marshall?

A. I was going to say me. If you are asking the question of who was in charge between Dr. Carter and Dr. Marshall, I think you should address that question to them.

Q. What is your impression?

A. I think I answered earlier that I worked with Dr. Carter on this like I did on other assessments.

Q. Are you saying he was in charge?

A. I am sayng if there is any question as to who was in charge between him and Dr. Marshall, one would have to address the question to the two people you are——

Q. I am asking you for your understanding.

A. What do you mean by in charge?

Q. Who took charge of this assessment, which of the two—which of your two superiors was actually in charge of this assessment and guided it along the way and decided when deadlines would be set and when they would be broken? Who was in charge of this assessment?

A. I would imagine that Dr. Carter has interaction with Dr. Marshall on all our work. I am not sure to what extent that changes from issue to issue. As I indicated earlier, Dr. Marshall was involved in this assessment more than others because he was personally involved in the issue, for other reasons that have been stated. So it is likely that he and Dr.—Dr. Carter and Dr. Marshall discussed this may be more frequently and there was more interaction. The extent of that——

Q. Out of your presence?

A. At times. I wouldn't be aware of that, then, if it was out of my presence.

Q. But Dr. Carter might have told you afterwards?

A. Yes; but, again, if he didn't tell me, I wouldn't know. He told me a lot of things as this went along. Dr. Carter and I discussed this issue at great length as the issue was addressed. Dr. Carter and I worked—Dr. Carter was no less involved in this than any other issue.

Q. But Dr. Marshall was involved in this issue more than others?

A. Yes, and probably Dr. Carter was also.

Q. What instructions did you receive at the outset of your assessment regarding your task and from whom did you receive these instructions? Did you receive all of them from Dr. Carter? Did you receive some from Dr. Marshall and some from Dr. Carter? From who did the instructions flow?

A. Dr. Carter.

Q. Exclusively?

A. As far as I recall, yes.

Q. I am going to ask you this question and hope it will jog your memory. Did you at any time, at that time, receive any specific instructions, I am speaking to the onset, the outset of the assessment, receive any specific instructions from Dr. Marshall that were apart and seemed to differ from those you received from your immediate superior, Dr. Carter?

Mr. RISEBERG. We are talking about in March?

By Mr. MICHIE.

Q. We are talking about when you received your assignment. I don't think you made that clear yet, as to when you were given your instructions initially?

A. To begin the assessment?

Q. That is right.

A. Sometime after the hearing. I don't remember the exact date. In fact, there was another colleague in the office who also helped to put together—collect information to prepare the testimony, Dr. Handelsman, and he was working on some other assignments and it just happened that Dr. Carter, because the two of us helped prepare the testimony, I imagine that—got involved early on for the hearing, that it was likely that one of us would be chosen to do the assessment. He felt that Dr. Handelsman—he wanted him to finish work he was doing and it was Dr. Carter's decision, as far as I know—chose me to work on the assessment. In terms of instructions, if there is something that occurred——

Q. I am just trying to jog your memory.

A. Let's be clear that Dr. Marshall was more involved in this, there is no question about that. If there were times when he said something that you are trying to have me remember, I don't recall any specific thing. If there were something I was already doing or in agreement with Dr. Carter, then it didn't change anything. If you can be more specific, I can answer it better.

Q. Well, what I am trying to do is get from you your recollections, if in fact at the outset of this assessment, when you received your instructons on what to do, whether or not you received any specific instructions at that time from Dr. Marshall that were apart and seemed to differ from those that you were receiving from your immediate superior, Dr. Carter?

A. I think I can answer that no.

Q. Let's now go on through the course of the assessment. Did you receive any such specific instructions from Dr. Marshall any time during the course of the assessment and all the way up to August 6 when the report was delivered to Dr. Windom?

A. That differed from the instructions of Dr. Carter?

Q. That were separate and apart from those you had been given by Dr. Carter. This might have had to do with the conduct of the assessment, with the amount of time that was being spent on the assessment, with meeting deadlines on the report, with how the report would be structured. Does that give you any help?

A. Yes; I will respond to those specifics. Conduct, I am not sure what you are asking. But, again, as far as I knew, instructions from Dr. Marshall were instructions, you know, that Dr. Carter would carry out. If we were asked to complete the assignment in a certain period of time which either came from—that came from Dr. Marshall to Dr. Carter—Dr. Carter might have agreed with me that, gee, it would have been nice to have more time but I am not sure if that is what you mean by disagreeing. The structure, no, the structure followed the Federal Register notice questions in terms of the findings and conclusions in the assessment—followed the scope that was developed for the Federal Register notice which Dr. Carter and I worked on a great deal and spent a lot of time on, and lot of that came from the hearing, as to the issue which should be addressed. That basically set the structure of the assessment. I went about this assessment as I would any other assessment and basically we know what we have to do and we go and do it. Almost all my conversations were with Dr. Carter as they were on other assessments.

Q. Did Dr. Marshall at any time during the drafting of the report ever come to you directly and make suggestions on changes, on what to put in, on what to take out or what to change?

A. I don't believe so.

Q. You are certain of that?

A. When you say drafting—Dr. Marshall modified the report as he would any report when he receives it. Let me clarify that. When any of our assessments go to Dr. Marshall, he will make comments. Our assessments go to Dr. Carter who makes comments. We would look at those comments and Dr. Carter and the analyst would decide how to deal with it. Sometimes we agree and sometimes we disagree.

You see, we were preparing a draft for Dr. Marshall and the draft that we prepared with the conclusions and findings and recommendations was modified to some extent, probably more so the conclusions and findings, there were some minor modifications, and the recommendations, when he looked at the assessment and he was responsible for sending it to Dr. Windom. So there were changes, yes.

I understood you to mean I was sitting in my office developing the report and Dr. Marshall came in and said write this or take this out or put this in. At the end he and Dr. Carter were going over the draft and making editorial changes, trying to fine tune it.

Q. Did you receive these from both Dr. Marshall and Dr. Carter?

A. Well, because Dr. Marshall received the draft very close to the time that he needed to present it to Dr. Windom, these things were kind of all done at once, and I was reading what they were writing. It wasn't a question of do you—you know, take this and what do you think about it. We were in the office and there was a lot of work going on, a lot of reading and re-reading—

Q. I understand.

A. But basically not on the basic report. More so on the conclusions, findings, and recommendations.

Q. Did you receive changes from Dr. Marshall as well as from Dr. Carter?

A. Dr. Carter read the report, made some changes and gave them to the secretary to incorporate. Dr. Marshall's comments Dr. Carter looked and dealt with them.

Q. Did Dr. Marshall not come to you or send to you changes for the report directly?

A. He got a copy of the report and made some notes that he was addressing to me, but Dr. Carter dealt with those comments.

Q. How do he deal with those?

A. He read them and I assume he addressed them. This was just before—Dr. Marshall wanted the report on August 1, for himself, and I believe he looked at the report—that was a Friday. He looked at it over the weekend, and he did have the report on my desk and Dr. Carter is the one, I believe, who dealth with that copy of the draft. I don't believe I dealt with that draft. It is possible. Things were going very quickly. We were making a lot of changes.

Q. Things were going very quickly, weren't they?

A. We were trying to get the report to Dr. Windom.

Q. You were trying to meet the deadline? There ~~was~~ a deadline certain, was there not?

A. Yes; there was. There was a meeting, and at that meeting in July, Dr. Windom indicated tht he would like the report, I believe the date was August 10. Dr. Marshall felt that he needed the report August 1 to get the time to get the report to Dr. Windom and as it turned out he wanted to get the report to Dr. Windom before the 10th, a few days earlier, so that we were moving as quickly as we could on the matter.

Q. Referring back to McDonald's memo, Dr. Macdonald made the following requests, "Please complete a review and provide me with your conclusions with respect to the safety, efficacy and cost effectiveness of dialyzer reuse within 60 days."

Now at the time you were assisgned to this assessment, did not question whether such an assessment involving both safety, efficacy as well as cost effectiveness could be completed within 60 days?

A. Yes.

Q. Tell me, what were your questions about that, and to whom did you put the questions?

A. My hope that more time could be allowed was addressed to Dr. Carter, and he said, we do the best we could.

Q. Did you also inform Dr. Marshall that you felt that this timeframe was unreasonable?

A. Those feelings I would convey through Dr. Carter.

Q. Did you convey that to Dr. Carter, that you felt that this timeframe was unreasonable—did you not?

A. Probably.

Q. Yes or no?

A. Based on the fact that other assessments take longer, I felt that it was unreasonable, but we would try and do it.

Q. And what specifically was the reaction of Dr. Carter to this again? I am sorry, I wasn't clear on that.

A. That Dr. Windom, or it was being done for Dr. Macdonald, that requested it. And that we would try and produce a report.

Q. Did you at that time remined Dr. Carter that NCHSR had never before done an assessment of this particular issue—did you remind him of that? Do you recall that?

A. Why would I——

Q. I am asking you——

A. Are you asking me did we ever do an assessment or did I remind him?

Q. Did you make comment to Dr. Carter that the information reposited in the files of NCHSR was rather skimpy on this issue, simply because no one had ever asked you to do such an assessment before? Wasn't that the case?

A. Such an assessment or an assessment in that period of time?

Q. An assessment on the reuse and reprocessing of dialyzer devices?

A. Absolutely. I had never done an assessment on that before. There was an assessment that I did that was somewhat related that had to do with the use of balloon angioplasty for dialyzer—access fistulas, when they block, and so if you are referring to that, I did do a somewhat related—but I was never asked nor did I ever work—in fact, it was the first time I heard of the subject matter.

Q. First time?

A. That the—yes.

Q. And to get back to my earlier question, isn't it the case that the files at the NCHSR were rather skimpy with regard to this whole issue?

A. Actually the files were probably better in this case than they would have been in any other assessment because when we receive a request from HCFA to do an assessment, the only thing that has preceded that is an agenda for a physicians panel meeting where decisions are made as to whether or not PHS will address certain issues. We receive very little literature and have very little time usually to look into the matter prior. So that in this case, because of the hearing, because of the interest, we probably had more material on this issue than we had on other——

Q. That you collected prior to the hearing?

A. That we provided to us in response to the hearing.

Q. But prior to the hearing, there was precious little in your files on this subject. Isn't that correct?

A. Yes.

Q. And, of course, you didn't learn that you were going to become involved in this hearing until, what, a week, 10 days before the hearing happened?

A. Involved in terms of writing an assessment or helping——

Q. Involved in gathering all this material that you say you gathered for the hearing?

A. Yes.

Q. It was just a matter of days, was it not?

A. When they found out that Dr. Marshall was going to be involved, yes.

Q. So you really, to begin with, didn't have that much time to gather the material any way, did you?

A. Correct.

Q. What was the original deadline for NCHSR to produce a draft report on the assessment?

A. Well, this says 60 days——

Q. That would have been June 10, wouldn't it?

A. Yes.

Q. The Federal Register notice was, when, May 10——

A. No; I believe sometime in April. I am not sure how much time that gave.

Q. Wasn't the comment period for 60 days?

A. I believe June 10 sounds correct, to try and have a draft. Up until then material could come in.

Q. And did you produce a draft to meet that deadline? Did you not produce a draft to meet that deadline?

A. I had a draft that never went beyond my office at that deadline. As you know, you came in with a great deal of material——

Q. But you did have a draft?

A. There was a report dealing with the subject.

Q. This may perhaps jog your memory. Are you aware that on June 9 I asked Dr. Marshall in a telephone conversation whether a draft assessment report existed? Did Dr. Marshall share that telephone conversation with you?

Mr. RISEBERG. Let's establish a foundation. Do you know anything about this phone conversation——

Mr. MICHIE. Pardon me. I will get to that. And Dr. Marshall informed me that there was a draft and it was going to go forward on June 10. Do you recall plans to that effect?

A. I am sure there were plans to that effect. I might not have been comfortable, would have liked more time, but I am sure Dr. Marshall wanted to meet his deadlines.

Q. You weren't at all confortable, were you, with the idea of having to give up the draft that you had at that time for transmittal to the Assistant Secretary for Health? You weren't at all comfortable with that were you?

A. I would have liked more time. However, the report that did go to Dr. Windom——

Q. We will get to that report in a moment.

A. You are talking about June 10?

Q. I am still talking about June 10.

A. At that time I would have——

Q. The June 10 version.

Can you tell us—Mr. Schulke and I visited your office and reviewed your files. We saw nowhere in those files a draft dated July 10 or 9 or whatever——

Mr. RISEBERG. June, you mean June,

Mr. MICHIE. I am sorry. Thank you.

By Mr. MICHIE.

Q. Is there such a draft and where is it?

A. The drafts that you had access to are the drafts that are available.

Q. I am talking about the draft on June 10, the one that existed on June 10—in fact, it existed on June the 9th did it not?

A. The draft that existed was subsequently worked on because of the additional time and more material—if there is no draft that says June the 10th, not knowing that someone some months later would be looking for it, then we——

Q. It does exist somewhere?

A. No, no. It probably didn't exist on June 11. What I am saying is when more time was given, the report was built on and material as added and—so what I am saying is there is no draft that says June 10. If there was, you would have it. If it was in there, then it exists. I didn't have a June 10 draft, and put it aside because somebody said we have all this material and it became an open-ended due date at that time. A lot of material came in. Dr. Carter indicated that we needed time to go through it, I believe, and I believe until the July meeting I wasn't sure when the report was going to be due and at the July meeting I believe it was confirmed that it would be due August 10, so that on June 11, I went to work, and, no, I didn't take June 10 and put it aside.

Q. You did not preserve a copy of the draft as it existed on June 9. You didn't do that?

A. I don't believe so.

Q. Did you throw it away?

A. If it is not in the thing, yes; at that time.

Q. You see, the reason why I ask that question is because, according to Dr. Carter, his office keeps what is called a draft file, a file of drafts. Are you familiar with that file? A file specifically dedicated to hold drafts?

A. It sounds familiar; yes.

Q. Do you think it is possible that your June 9 or June 10 version of this report would be in that file?

A. No; I don't believe so.

Q. But you are not certain?

A. No; I couldn't be certain. I haven't looked.

Q. Is the reason why you don't think so because you threw it away?

A. Between the time I started on this report until today I have thrown many reports away as I add material.

Q. So, it is possible you did throw it away?

A. Yes.

Q. What was the deadline for submitting comments in response to NCHSR's April 10, 1986 notice in the Federal Register? I believe that solicited comment on dialyzer reuse?

A. I would rather look at the Federal Register, but I believe June 10.

Q. Does that sound right to you?

A. Close to it.

Q. June 10?

A. Are you telling me that is what the date was?

Q. That is my recollection. So we agree.

A. OK.

Q. The NCHSR assessment report was forwarded to Dr. Windom, the Assistant Secretary for Health, on August 6. Is that correct, August 6?

A. Close enough. I believe so. Was that a Wednesday—something like that—yes.

Q. August 6?

A. It sounds right.

Q. That was the date of the cover memo?

A. Yes; it sounds right.

Q. Once again, I want to understand you clearly. This was in response to the deadline imposed on NCHSR, is that correct, deadline imposed by——

A. Dr. Windom, I would imagine.

Q. Do you recall my having met with you privately in the conference room across the hall from Dr. Marshall's office on the morning of August 6? Do you recall that?

A. Yes.

Q. Didn't you admit to me during that meeting that more time indeed was needed to do an adequate job on the assessment? Did you not admit that to me during our private meeting?

A. I don't remember exact words. If you say so, I will take your word for it.

Q. In words to that effect, did you not tell me that you felt more time should have been spent on this assessment?

A. Again, I don't remember. We discussed a number of things you mentioned. You had some material. I think I have said already here that, you know, earlier on, more time would have been nice.

On any assessment you would like to have more time if you feel there is a lot of material to cover.

Q. Do you recall my having—do you recall my having offered to NCHSR a large stack of documents pertaining to establishment inspection reports from the FDA regarding reprocessing and reuse issues, documents that FDA had not provided to NCHSR for consideration in the assessment on that same day?

A. I believe that is what you indicated.

Q. There was a large stack of documents sitting on the table where we were sitting?

A. I believe that is correct.

Q. But, of course, it was too late for you to deal with those documents on that morning, wasn't it?

A. What do you mean by that?

Q. Because the report was being sent to Dr. Windom on that same day so there was no way for you to consider this stack of documents that I had brought over to share with you so that they might be considered for the assessment. Wasn't that the case?

A. Every assignment has deadlines, and this one the deadlines had changed previously and this was the latest deadline. Dr. Marshall wanted to meet this deadline. Dr. Marshall I think felt comfortable with our findings and conclusions and recommendations and felt that comfortable sending the report as is to Dr. Windom. You would have to speak to him as to specifically why he chose to do what he did.

Q. But my question was on that morning, when I brought you that large stack of documents, the fact is you could not have considered them then because it was too late. The report had to go?

A. If the report was going to go to Dr. Windom on time, then that material could not be read, reviewed and incorporated.

Q. Didn't you later tell me that prior to my having brought those materials over there, that had not seen any of it?

A. When did I tell this to you?

Q. In a telephone conversation a couple of days later. Did you not tell me that?

A. We have received much material. We have received material that you had provided us that are from the FDA that we had not seen before. Whether it was all of that material, some of it, I would have to have the material. But, yes, there is material——

Q. Substantial amount of material?

A. There are reports that I had not seen before.

Q. Didn't Dr. Marshall bring into work with him on the morning of August 4 a collection of documents, documents that I had delivered to his home along with a cover memo dated August 2 including reuse problems and injuries, most, if not all——

A. Can you repeat that?

Q. Medical device reports on reuse problems, most if not all of which had not been provided to NCHSR for the assessment? Do you recall that stack of documents that he brought in to work with that morning?

A. Dr. Marshall did bring in a stack of documents on that morning; yes, he did.

Q. Did you see the cover letter bearing my signature?

A. Probably.

Q. You have that in your files, don't you?

A. I should.

Q. Didn't Dr. Carter, your superior, at that time, after receipt of those documents, suggest that at the very least some of these FDA documents pertinent to the assessment should be appended to the report? Didn't he make that suggestion?

A. To me?

Q. Didn't he discuss with you the possibility of appending some of those documents, if not all of them, to the report, simply because there was not time enough for you to read them and to include any of the information from those reports? Did he ever discuss that with you?

A. Usually when Dr. Carter——

Q. Please; yes or no.

A. I don't recall. Thinking back, I can't answer that yes or no. Usually when Dr. Carter would like something done, it is done. If he wanted those reports appended, they would have been. He might have said that. I don't recall. He might have decided to put a statement in the assessment at the end that might have been instead of appending reports. It is possible he said that. I really don't recall. Usually when he knows what he wants to do, it is done.

Q. Let me jog your memory. Did Dr. Carter not come to you and inform you that he had made such a suggestion to Dr. Marshall but that Dr. Marshall said that he didn't feel that it was necessary?

A. It is possible. I really don't remember.

Q. You just don't recall?

A. I don't recall.

Q. Do you recall my having visited your offices along with Mr. Schulke on August 14 to review your files pertaining to the assessment? Do you recall that?

A. Yes.

Q. Didn't you on that occasion inform Mr. Schulke and I that while it took on the average of 9 months or more to complete a health technology assessment, the reuse issue was indeed very complicated and so, therefore, much more time should have been spent on this assessment? Did you not inform us of this on that date? Did you not state that to us on that date? Didn't you tell us as we stood up in the outer office of Dr. Carter's office that you felt that just the formaldehyde issue alone was extremely complicated, let alone all of the other issues involved in this particular assessment?

A. I am not sure how much of what you are repeating is what I said or what you are adding to. Some of what you are saying is certainly——

Q. I am taking from my notes of your conversation, and I stood there and took notes as you spoke. Now do you recall that?

A. If you had asked me questions of how long an assessment took, I would answer the same as today, the answer is 9 months, and if you knew how long we worked on that assessment, then it is certainly true that more time would have been nice. Sometime you don't have the luxury of time.

Q. Is it that you don't recall?

A. It is possible I said that. If you took notes—I don't recall you taking notes of our conversation. I might not have had the conversation.

Q. Be that as it may, even if you don't recall having said that, at that time, on that particular date, you did in fact feel that way, did you not, that you did need more time if you were going to do a thorough and adequate job on this assessment?

A. Yes; however, I feel that we did provide a thorough and adequate finding and conclusion and recommendations that went to Dr. Marshall, regardless of the time that was allowed to us. The findings and conclusions of the OHTA assessment with its recommendations that went to Dr. Marshall resulted from the work that we put in, regardless of the time, and I believe that they are substantial.

Q. Nonetheless, Mr. Erlichman, you stated under oath a moment ago when I asked you the question of whether or not at that time, regardless of whether you recall our discussion about it, that you felt at that time you did indeed need more time in order to do a thorough and complete job on that assessment, and your answer to me a momment ago was yes. Is it still yes?

A. Yes; I would have liked more time—yes.

Q. Referring again to Dr. Marshall's March 5 memo to—Dr. McDonald's March 5 memo, the first sentence says, the cost implication of the variance in current practice for the use of dialysis supplies are of interest to HCFA and the Congress as well as the PHS.

I have taken the liberty of paraphrasing a bit but I don't think I have taken anything out of context. Is that your reading of that?

A. Yes.

Q. Were you made aware at the outset of the assessment or at any time thereafter of why HCFA was interestred in these cost implications, and if so, from whom did you receive this information and what were you told?

A. Could you repeat and break it up so I am clear on what you are asking?

Q. Were you aware at the beginning of this assessment or at any time thereafter during the course of the assessment——

A. You are spreading that out so it might be difficult to answer you from over the course of the assessment.

Q. Well, if it was before, or at the outset, or during, the assessment that you became aware of why HCFA was interested in those cost implications.

A. Yes.

Q. Were you aware of that, and if so, when did you become aware of it, was it at the outset or sometime during the assessment itself?

A. Earlier you asked me if I was familiar with this memo, and I said I might have been but there were some things on there that I didn't recall. That is one of them because at the onset, in fact most of the way through, I don't believe I was aware of the relationship between the assessment and its use by HCFA for any decisions for reimbursement until much later on.

Q. When?

A. I am not exactly sure. Probably when I was made aware of some memos or letters between the Secretary and the Senator regarding the reimbursement issue for reuse. I believe that until that time—as you know, the report was going to Dr. Windom. It did not come through the normal channels of HCFA, and as far as I understood it, the report was to him trying to answer the questions that we had identified in the Federal Register notice. Though we mentioned cost, the dealings of cost would show whether reuse was economical. That was the only area relating to cost and so, I felt that that was the material that was being requested and why it was being requested.

Q. That reuse could save money. Is that correct?

A. Excuse me?

Q. Was that one of the issues, that reuse could save money, it had potential for saving money? Isn't that correct?

A. That is the issue that was developed at the hearing.

Q. But was that the understanding you had with regard to this phrase about cost implications?

A. Cost implications is not mentioned in our Federal Register notice. You know, I dealt with what you see in the report. We did not do a cost benefit type of analysis in the report.

Q. You didn't?

A. Did you see one?

Q. Not to my recollection. No, I don't think so. Were you ever asked to? Was it that you were asked to do so but you ran out of time?

A. We developed the material in the seven or eight areas of interest in the Federal Register notice and that is what we dealt with, and everyone was aware of that and I assumed everyone was satisfied with that.

Q. Did anyone at any time during the course of the assessment state to you or give you the impression that this assessment of dialysis reuse was not a regular assessment, that it had to be done in a hurry, and if so, who was it that stated this to you, that it had to be done in a hurry, that it wasn't a regular assessement?

A. Well, it wasn't a regular assessment because it came from the Assistant Secretary instead of from Health Care Financing Administration.

Q. What I mean by regular is, it wasn't regular in the sense that you were asked to do it within an unreasonable timeframe. That is what I mean. Isn't that the case? You yourself used the term unreasonable about 45 minutes ago.

A. What is your question again?

Q. My question to you is did anyone ever state to you or give you the impression that this assessment, dialysis device reuse, was not a regular assessment in the sense that it had to be done in a hurry, within an unreasonable timeframe?

Mr. RISEBERG. I don't recall the word unreasonable being used. Is there a need to check that?

Mr. MICHIE. If you would like, we can check it later.

By Mr. MICHIE.

Q. Please answer the question.

A. I don't recall somebody——

Q. You don't recall——

A. No, no, excuse me.

Q. Go ahead. Please.

A. The last part of your question is that it has to be done in a hurry?

Q. That it had to be done in a hurry. The first deadline you recall was June 10?

A. If any comments were made, it was that the deadline was being set by the people in the Department and that we would try to meet it.

Q. And that you had to do it in a hurry?

A. If assessments usually take 9 months and we had to do it in 2 or 4 months, then we had to try to do it quicker.

Q. But at the time of the assessment——

A. I said between 2 and 4 months.

Q. It was 2 months. No one mentioned 4 months back than?

A. I agree.

Q. As a result of that you were being given a third of the time that you would normally be given. Not only that, this was an unusually complicated issue, was it not?

A. We have other complicated issues, but this had many issues to deal with, yes.

Q. And it was very complicated, as you stated to me on the afternoon of the 14th, as we stood in that office?

A. May I see your notes?

Q. I don't have them with me.

Mr. RISEBERG. Do you want to provide them for the record?

Mr. MICHIE. I am going to rely on his recollection.

Mr. RISEBERG. He answered he doesn't recall.

The WITNESS. What is your question?

By Mr. MICHIE.

Q. At the time you were given this assignment you were given 2 months which is a third less than the time you would ordinarily be given. On top of that this was an extemely complicated issue.

A. What is your question?

Q. At this point my question is do you feel at that time the timeframe was unreasonable?

A. Yes; I do.

Q. Did anyone at any time during the course of the assessment inform you that completing the assessment and a report as soon as possible was important to HCFA because that agency was preparing to publish a proposed regulation to reduce Medicare's dialysis reimbursement rates and if so, from whom and when did you receive this information?

A. I don't believe so.

Q. Do you have a definite recollection of not having been told this by anyone?

A. That it was important to HCFA?

Q. Yes; because of their proposed regulation.

A. As I stated earlier, it was my understanding that the material was going to the Assistant Secretary dealing with the issues that we outlined in the Federal Register notice. None of those issues dealt with matching down the reimbursement. So I don't have a recollection of somebody telling me, and the fact that it wasn't dealt with in the assessment, until much later, may be when the draft went to Dr. Marshall, like I said, when people started—when I saw some of the—in fact, it might have been at the earlier deposition when you showed me a memo or letters between the Secretary and the Senator.

Q. During the course of the assessment, with whom did you have occasion to communicate on any aspect concerning the assessment? First let's say within the Executive Secretariat of PHS? Did you have occasion to communicate with anyone there?

A. Who might that be? I am not sure.

Q. I am asking you. I assume that if you communicated with someone there you would know. Would you like to look at your notes or your calendar?

A. I wouldn't have that in my notes. What does during the assessment mean, up to this morning?

Q. The assessment was delivered on August 6.

A. There might have been some conversation when your staff started requesting material and there might have been some phone calls. Normally Dr. Carter would speak with people downtown.

Q. You didn't——

A. It is hard to differentiate that between recent discussions regarding the depositions and such. If you can be more specific, I can try to answer it.

Q. I am asking you as to whether or not you had any conversations during the course of the assessment, all right, with anyone associated with the Executive Secretariat of PHS? Did anyone call you, did you have occasion to call them?

A. I don't recall. Excuse me.

Mr. RISEBERG. We can say for the record the Executive Secretariat of PHS is an office that handles correspondence for the Assistant Secretary for Health.

Mr. MICHIE. Who are some of the people that have worked there?

Mr. RISEBERG. The head of the office is Robert Rickard.

By Mr. MICHIE.

Q. Does that name——

A. I have heard the name. I don't believe I have spoken with the gentleman.

Mr. RISEBERG. I don't know who on the staff is dealing with the reuse issue.

The WITNESS. Over the course of this assignment I have spoken to many people. It is possible but I really don't recall.

By Mr. MICHIE.

Q. How about the FDA, with whom did you speak there on any aspect?

A. Larry Kobren, Bob Eccleston and Dr. Villarroel.

Q. Anyone else?

A. Yes; I don't recall their names. Somebody in compliance, I think and recall, if those are correct divisions of FDA. There might be others but that is what I——

Q. Did you ever have occasion to speak with a Ms. Marie Reid?

A. Yes—well—yea, I believe so. I might have called at times when she wasn't there and spoke to someone else but it was someone I wanted to speak with.

Q. How about Mr. Villforth?

A. No.

Q. Benson?

A. If Mr. Benson was at the—I think he was at the July 6 meeting in Dr. Windom's office.

Q. July 8 meeting?

A. July 8 meeting. Thank you. It is possible we spoke a few words.

Q. Were you at that meeting?

A. I was.

Q. What about the CDC, with whom did you discuss any aspect of the assessment there?

A. Dr. Favero, Dr. Murphy, Dr. Solomon.

Q. Dr. Solomon?

A. Yes. May be—that is basically what I remember. There might be others.

Q. Dr. Moritone?

A. I don't think so.

Q. Dr. Mason?

A. It is possible that I was present in Dr. Carter's office during some calls to CDC. If those were the gentlemen on the phone, then I might have had some contact. I don't recall.

Q. How about the NIH?

A. I have spoken to one or two people at the NIH regarding the assessment.

Q. Do you recall their names?

A. I asked Dr. Heyse to send us a report?

Q. Dr. Heyse?

A. Yes, to send a report, Steve Heyse.

Q. Which report?

A. To send us a publication on evaluation of hemodialyzers that was done some years ago, and he did.

Q. Anyone else?

A. Yes, but I don't recall their names, just getting——

Q. Dr. Striker?

A. That is possible. Is he at NCI in epidemiology—no, I heard that name somewhere else. I spoke to one or two epidemiologists at NIH.

Q. What about Dr. Hirshman?

A. Again, probably when they were preparing the testimony there were numerous phone calls back and forth between Dr. Carter and people at the agencies that were familiar with the issue. I very likely might have been present in the office and listened or made comment. I don't recall who exactly was on the phone. I did pick up some material at NIH also for the report, I believe, the Deane report, I think I went over and picked it up, relate to go the hearing preparation.

Q. HCFA, anyone at HCFA?

A. I don't believe I called anyone at HCFA.

Q. What about someone calling you?

A. Let me take that back, because I was interested in mortality data for patients on dialysis so I did call because they run the end stage renal disease program and I did try to get the name and phone nmber of somebody who could provide that information, Dr. Krackower, and I did deal with people dealing with end stage renal disorder. So, yes, there was some contact, I believe, in that area.

Q. National Nephrology Foundation?

A. If that would be Dr. Deane, there was—are you talking about contact, telephone, personal?

Q. Whatever, meetings——

A. Is that who you are referring to? We did receive materials from these groups. Also some groups came to OHTA. That was the renal physicians association, I believe, that came. Some of these people are in more than one organization.

Q. Did you speak with Dr. Deane?

A. Yes.

Q. You did?

A. Yes, sir.

Q. When?

A. I don't recall the exact dates. He was at OHTA.

Q. Who else was present?

A. At least Dr. Carter.

Q. Did you speak with Arthur D. Little?

A. I don't believe so. We have their report but I don't believe I had any personal contact, that I recall.

Q. Phone or otherwise, nothing, right?

How about AAMI?

A. You asked me a question. Let me think. I am trying to think of a lot of people over a lot of months. I don't believe so.

Q. Do you have a definite recollection of not having done so?

A. No.

Q. So it is possible?

A. Anything is possible.

Q. Do you recall having visited this committee office on April 17, 1986?

A. I recall having visited this committee office. I will take your word for the date.

Q. Along with Dr. Carter and I think there was another person with the two of you, was it Dr. Handelsman?

A. If it was, he is the gentleman I referred to earlier.

Q. What was the purpose of your visit?

A. Since you probably arranged that with Dr. Carter, he or you would probably be better able to answer that. I assume to obtain what information we could since we were obtaining information from all sources for the assessment, and I think you indicated that you did have—you were in possession of a lot of material. If there were other reasons, I don't recall.

Q. Did the three of you meet with committee staff to discuss the committee's investigation findings on dialyzer reuse? Do you recall any discussion on that?

A. I imagine that would have been discussed.

Q. Do you recall a discussion?

A. I don't recall the exact discussion.

Q. Do you recall sitting around this very table with Dr. Carter, myself, and Mr. Cunningham?

A. Yes, I do.

Q. Were you given the opportunity to review documents pertaining to the committee's investigation?

A. Yes, we were.

Q. As a matter of fact, we brought quite a bit of documentation in here, didn't we, and placed it on the table, so all of you could take a look at it. Do you remember that?

A. Yes.

Q. Was there anything that you learned from your visit, from these documents and from discussions you had with us?

A. I don't recall what those documents were exactly. If you would be more specific I could answer that. I have learned a lot over these past 4 or 5 months dealing with this issue. What I learned specifically at that meeting, I don't recall. I know your staff went into some detail about the issues I think that were raised at the hearing.

Q. What I am getting at principally is, isn't it a fact that there were a number of documents that we shared with you, documents that were reposited in the Department's own files, within PHS's own files, that you had not seen before, that related to this issue? Wasn't that the case?

A. I am not sure—when you say PHS files——

Q. Yes; documents from FDA, documents from CDC, documents from the Department itself, documents from NIH. You don't recall seeing documents that we provided to you that you had never seen before?

A. At that time, which was early on in the assessment, there were probably many things that we didn't have and were glad to get material from anybody. If you had documents from these organizations at that time, that were not provided by those organizations later on, that is possible. I am not sure. Did we sit here and read through all those documents? I don't recall.

Q. As I recall——

A. Did you provide them to us?

Q. The three of you sat here for the better part of a day reviewing these documents. As a matter of fact, following your review, you identified for us those documents you did not have that you requested copies of, and we did provide them to you. You don't recall that?

Mr. Riseberg. Are you testifying to that effect?

Mr. Michie. I am asking a question, counselor.

The Witness. I recall that you were going to provide us with material, yes.

By Mr. Michie.

Q. Would we have provided you wth copies of things you had already had?

A. Probably not.

Q. Didn't you and Dr. Carter discover during that visit to these offices on April 17 that there were serious questions regarding the validity and integrity of the NIH sponsored report, "Multiple Use of Hemodialyzers"? Do you recall that?

A. Can you repeat the question?

Q. Didn't you and Dr. Carter discover during that visit to these offices on April 17 that there were serious questions regarding the validity and integrity of the NIH sponsored report, "Multiple Use of Hemodialyzers"?

A. A great deal of that meeting that you are referring to did deal with that report, the Deane report and you showed Dr. Carter——

Q. Please continue.

A. And you showed Dr. Carter statements that were made in the report and letters, I believe, from Arthur D. Little and possibly a second report from the NIH, identified as a revised report, may be dated 1982. I believe you and Dr. Carter had a great deal of discussion on that.

Q. And you were privy to that, were you not?

A. I certainly was. You are asking about the—both of you, I think, addressed the validity and the——

Q. Integrity?

A. Integrity of the report. I believe there was some controversy regarding that report between Arthur D. Little, and Dr. Deane.

Q. We will get to that in a moment.

Are you aware that Dr. Marshall as principal witness for the March 6 hearing relied on the Deane report, as it is known, to support the PHS position that reuse is safe? You are aware of that, aren't you?

A. Probably.

Q. Would you like to see his testimony in order to refresh your memory?

A. If it is in his testimony, I would be glad to see it.

Q. Let's take a 5-minute break and we will get that.

Off the record.

[Discussion off the record.]

[A recess was taken.]

By Mr. MICHIE.

Q. I believe you have before you a copy of Dr. Marshall's prepared statement. Are you turned to the page that has the heading reuse safety?

A. Yes; that is correct, page 3.

Q. Would you look down toward the middle of that section and does it not refer to the report that we have been discussing, "Multiple Use of Hemodialyzers"?

A. Yes.

Q. And does he not use that report to support safety of reuse?

A. Dr. Marshall has, so have many other people.

Q. Let me provide you now with a letter dated October 9, 1981, to Dr. Norman Deane, principal author of "Multiple Use of Hemodialyzers." Wasn't this one of the documents we shared with you on April 17 when you visited here?

A. Probably.

Do you recall having seen it here?

A. I have a lot of the material regarding Arthur D. Little and Dr. Deane and I believe the report was contracted to the—National Nephrology Foundation. We also have copies of materials sent to you correcting—commenting on Arthur D. Little's comments on the report. We received copies from Dr. Deane and other associates of his that were sent to the committee. So there is much material on this and we probably have most, if not all, of it.

Q. Do you recall our having discussed that here on April 17?

A. There was discussion on that point, yes.

Q. On the letter that you have before you?

A. I don't know if this letter per se, but there was material that was discussed. It is possible, yes. I know the report was discussed and there were some other points that were made.

Q. Are you aware that ADL was a subcontractor on the "Multiple Use of Hemodialyzers" report and performed most, if not all, of the research?

A. I know Arthur D. Little was the subcontractor. How much of the work they did I think is one of the controversies. But I know they were the subcontractor.

Q. Have you read the report, the Arthur D. Little report?

A. I looked at it.

Q. "The In-vitro Evaluation of Certain Issues Related to the Multiple Use of Hemodialyzers," did you read that report in its entirety?

A. I looked at parts of it awhile ago.

Q. So you did not read it in its entirety?

A. I might not have read the entire thing.

Q. Only parts of it?

A. It has been awhile. I know I looked at it. How much I looked at, I don't recall.

Q. Getting back to the October 9 ADL letter, isn't this letter sharply critical of Dr. Deane's report to the extent that ADL accuses Dr. Deane of misrepresentation and malinterpretation of his report?

A. Do you want to refer to any paragraph in particular?

Q. I am characterizing the letter, as I am sure you have read prior to coming here today, and I am using the words misrepresentation and malinterpretation as a characterization. Those words are not in there but if you would like to read the letter in its entirety, you are certainly welcome to.

You can point out in the beginnning ADL did not give the firm the opportunity to review Dr. Deane's report.

A. I understand that was a controversy between the two groups.

Q. Let the record show that Mr. Erlichman is reading the letter to Dr. Deane.

[Pause.]

A. I have briefly looked at the letter.

Q. Are my characterizations inaccurate?

A. I would prefer to say that for the record what Arthur D. Little is saying here is what they are saying, rather trying to interpret what you mean. They say the report fails to make clear where material referenced to Arthur D. Little and other authors' works begins and ends. They make a second point saying, we urge that conclusions which could be applied to clinical practice, such as those relating to the concentration of formaldehyde used for sterilization, be substantiated where appropriate by clincial trials, as was envisaged in the original request.

And he goes on to say, the final report omits most of the limitations which attended data and statistical statements in the Arthur D. Little report.

Q. What else does it say, toward the bottom?

A. In particular, the final report——

Q. Tacitly——

Mr. RISEBERG. I guess it could be.

The WITNESS. If you have a better copy, I will take your word for it. Tacitly asserts that the dialyzers which the National Nephrology Foundation submitted to Arthur D. Little for testing were sufficient in number and representation to permit conclusive statistical comparisons. The ADL report makes no such assertion, and in fact advises in several places that more extensive testing be performed to substantiate its qualified findings.

By Mr. MICHIE.

Q. What does he state on the last page?

A. There are a number of tables presenting data or statistical conclusions in the report which are attributed to the ADL report, when in fact the tables either in total or in part, are not derived from the ADL report.

Q. Is the word "not" underlined?

A. Yes; it is.

Q. So what do you make of this letter, Mr. Erlichman? Is it not sharply critical of the report that was issued?

A. Many of the——

Q. Please, yes or no. Is it not critical?

A. I find it—is it critical of the——

Q. Is it critical of the findings——

A. Is this letter critical of the report, yes, it is, based on what Arthur D. Little says.

Q. You stated earlier that you were present at a meeting involving Dr. Carter and Dr. Deane. Is that correct?

A. Yes; I did state that.

Q. When approximately did this meeting take place—did you not state that a little earlier?

A. Absolutely. I am shaking my head because I don't recall when it took place.

Q. It was during the course of the assessment, wasn't it?

A. Yes.

Q. Do you recall——

A. In fact, if it was once or twice—if he was with the renal physicians association, then he might have been at that meeting also. I would have to check that.

Q. I am talking about the meeting at which Dr. Carter and Dr. Deane discussed the Arthur D. Little criticisms, charges, relating to the way Dr. Deane had interpreted—the Arthur D. Little data?

A. That was discussed. I was not there for the entirety of the meeting. I had to leave at 4:30. The meeting went beyond 4:30 but some of that discussion took place before I left. Dr. Carter and Dr. Deane were discussing the report.

Q. Are you aware that your superior, Dr. Carter, in his meeting with Dr. Deane, raised questions, the same questions raised by the ADL letter, and that according to Dr. Carter, Dr. Deane was unable to refute the ADL complaints and charges? Are you aware of that?

A. Not the way you state it, because Dr. Carter, I don't believe, went into each of these issues——

Q. But you weren't there for the entire meeting?

A. I said for the parts I was there. Otherwise I couldn't answer to the parts I wasn't there. You would have to ask Dr. Carter when he appears for his disposition.

What I recall is the point that—I believe what the discussion between Dr. Carter and Dr. Deane was whether or not he could substantiate his statement without clinical trials or other studies, clinical studies, and I think he got Dr. Deane to agree with him that clinical studies might be appropriate——

Q. Might be?

A. I don't remember—he told me that he felt that Dr. Deane did agree with his position, and I believe it centered on the fact, and I think that was the main emphasis of Arthur D. Little's point, though I didn't get involved in that—tried to stay away from that controversy between Arthur D. Little and the National Nephrology Foundation. I believe the conclusion of the report which people have quoted that was based on in vitro studies, I think that criticism has been that they feel that the followup of clinical studies would validate those findings in the report and they shouldn't be based on just in vitro work. I believe that was the emphasis of the discussion. It is possible other areas were discussed as well.

Q. While you were present during that meeting, do you recall Dr. Carter asking Dr. Deane to explain what he had done with the tables, the tables of data?

A. No; it is possible I was there and I don't recall.

I don't recall that discussion or Dr. Deane's response. It is possible Dr. Carter—he did refer to a number of things and I don't recall Dr. Deane's response.

Q. Is it possible you were not there when they discussed the tables? Is that correct?

A. Yes.

Q. Let me refer to page 6 of the assessment report that was forwarded to Dr. Windom on August 6. At the second line from the top of the page, it reads as follows:

> Nephrologists have been persuaded by data of Deane and others that reprocessed hemodialyzers maintained states of cleanliness, function and sterility, (high level disinfection) which is equivalent to the first use dialyzer."

My question to you is shouldn't this passage, in light of the controversy over the Deane report, shouldn't this passage have begun by stating although there is substantial controversy or serious question regarding the validity and integrity of the Deane report and its findings, nephrologists have been persuaded? Wouldn't that have been more accurate?

Mr. RISEBERG. I think the record should indicate that two names were omitted.

Mr. MICHIE. I included the phrase "and others."

Mr. RISEBERG. Gotch and Kant.

Mr. MICHIE. We are discussing the report by Dr. Deane.

By Mr. MICHIE.

Q. Would you agree that that qualification should have been added to that phrase?

Again, although there is substantial controversy or serious question regarding the validity and integrity of Dean's report, nephrologists have been persuaded, et cetera.

A. This statement was made to show why there had been an increase in the reuse of dialyzers. It was not attempting to put any value judgment. You are saying nephrologists have been—but we have in the literature that there was a high percentage of facilities that reuse. It is work by Deane, Gotch, Kant, and others that have been published that persuaded nephrologists who have not been involved in the research to reuse in their facilities. That was the only intent.

Q. In citing the so-called Deane report as you did, once in the assessment report——

A. I believe it is cited twice.

Q. We only found one.

A. It is cited because—it might only be cited once. The State of California cites it for some of their findings in their preparation of regulations for dialyzer reuse. So indirectly it is used in that way. I tried to stay away from this controversy because I could have spent 2 months trying to learn and understand and read Arthur D. Little's claims and Deane's claims. It seemed that the main controversy was that Dr. Deane was making these statements on in vitro work and that clinical trials—people who felt that wasn't sufficient, they felt that clinical trials should have been carried out. Based on that, I tried not to have the report or myself get involved in that because I felt I could not deal with the other issues that needed attention, and as you stated earlier, they were complicated and many.

Q. Isn't it the case, Mr. Erlichman, that very few people, especially in the nephrology community, know anything about this controversy?

A. I wouldn't be in a position to answer that.

Q. I would like to refer you back to the Arthur D. Little letter and I would like you to read from the last page of that letter, not the attachment, the letter itself. What does he ask Dr. Deane to do there? Would you read that for us, please. He makes a request.

A. Since our report to the National Nephrology Foundation is a major reference, we hope that it, this letter and the attached comments, will be made readily available to those receiving copies of the final report.

Q. Were they?

A. I really don't know. I assume that you are indicating that they were not.

Q. Do you know if they were?

A. I don't believe so. If you are referring to the copy of the report that we have—there is the National Nephrology edition. There is the final report to NIH, there is the revised——

Q. They are all identical.

A. I don't believe this was attached. I see Dr. Wineman who is the project officer did receive the material and maybe you should refer some of these questions to him.

Q. In citing the so-called Deane report, why didn't the NCHSR assessment report at the very least mention that the Deane report had been seriously challenged by the research subcontractor, ADL, as early as 1981 and that this controversy is yet to be settled? Why didn't it mention that?

A. I chose not to. I just didn't.

Q. Why not?

A. I already stated. There was an an ongoing controversy. You stated it has yet to be settled and getting involved in it would have required a great deal of time and the time was required to do the other areas. I chose not to.

Q. I am not suggesting you should have tried to settle the issue. What I am asking is why didn't you at the very least mention in that report that it had been challenged and there was question about it as early as October 1981 and that this controversy had yet to be settled? Why didn't you mention that?

A. I didn't.

Q. Did anyone ask you not to?

A. No.

Q. Was this a decision on your own?

A. I believe it was.

Q. Is it possible that the reason why this particular piece of information wasn't included in the report is because NCHSR, someone in that agency, or someone in PHS, didn't want to offend or embarrass NIH since that agency had sponsored the Deane report. Is that a possibility?

A. The inclusion of the material in this report was my decision——

Q. Please respond to the question yes or no. Is it possible that the NCHSR——

A. It is not possible because I decided what went in here. Nobody called me up and asked me to include it or not include it.

Q. Could you possibly have thought in the back of your mind about not wanting to offend or embarrass NIH since that agency had sponsored this report?

A. No; I don't believe so.

Q. Are you aware that Dr. Deane is associated with the Manhattan Kidney Dialysis Center?

A. I believe so.

Q. Do you know whether or not that center reuses dialyzer devices?

A. I believe they do.

Q. Again, I will ask you, have you, or to your knowledge has anyone else at NCHSR discussed the Deane report with anyone at ADL?

A. You asked that more than once. Me or anybody else?

Q. Yes. Now I am asking you if you or anyone else, to your knowledge, have you or anyone else discussed with ADL——

A. To the best of my knowledge, I don't believe so.

Q. Why wasn't it discussed? You discussed it with Dr. Deane. Why wouldn't you discuss it with ADL?

A. It hadn't come up.

Q. No. I am trying to get at the point that you did take the time and trouble to discuss this controversy with Dr. Deane. I am asking you why didn't you get the other side of the story? Why didn't you go to ADL and discuss it with them?

A. There was no attempt to resolve this controversy. You look at the comments by Arthur D. Little. They are substantive and would require a great deal of time and effort and I guess I decided that it might not benefit the document to try to get the document out, to try to deal with the other issues that were pertinent. I guess it was because I felt that a major area of criticism of the Deane report, not necessarily by Arthur D. Little, but generally, was the lack of clinical trials. Based on that I tried to deal with clinical information in the assessment.

Q. I understand that.

A. That is the reason——

Q. Why you didn't to ADL, and why you didn't rely on the ADL letter dated October 1981? Didn't it ever enter your mind or cross your mind that perhaps you ought to call ADL to see how they felt about this issue in 1986? Didn't that ever cross your mind?

A. The emphasis in the report stemmed from the emphasis that was brought out at the hearing. That is reflected in the Federal Register notice and we felt we were dealing with the issues. The issues seemed to go beyond the in vitro work in some cases. People were interested in clinical information and that might be why we did not go back to Arthur D. Little and the in vitro material. If Dr. Deane initiated a meeting, if he attended the renal physicians—if he was in attendance at the meeting with the renal physicians association and followed that up with a request to Dr. Carter to come in for a meeting, that was quite possible. I did not seek out Dr. Deane to clarify his report for my assessment. I tried to stay away from that controversy.

Q. I understand, and I don't wish to make you repeat yourself. But could it possibly have been, one of the reasons, could it possibly have been that you just didn't have the time to try to deal with this issue because you at that point were looking down a very short tunnel, a 60-day deadline, and the light was very bright at the other end and you didn't have time to get into this issue? Isn't that possible?

A. Anything is possible. If I had more time I could have done things that I was working on and I could have done things I hadn't done. Anything is possible. But if I had thought that was crucial to the outcome, if I would have thought that, you know—as I said before, I think our findings and conclusions and recommendations adequately address the problems that have been raised and give good direction to the Public Health Service, and I don't believe that this would have—that this would have modified that, based on the—the controversy that seemed to exist.

Q. If you had had the time, if you had had the time as a health sciences analyst, performing what you would hope to be a very thorough analysis, would you have not wanted to at least check in with Arthur D. Little to ask——

A. Yes.

Q. Do you recall Senator Heinz having submitted to NCHSR on June 9, 1986 a voluminous response to the April 10 Federal Register notice? Do you recall that?

A. Yes.

Q. Did Senator Heinz' submission affect in any way the timetable for completing the assessment?

A. Yes.

Q. In what respect?

A. I believe that Dr. Carter either directly or through Dr. Marshall indicated that this material was presented and said that the report should not go forward until we looked at this material and the report was not sent to the—was not given to Dr. Marshall to send to the Department.

Q. That would have been the draft that you had at that time, as of June 9——

A. June 10.

Q. June 9 is when we made the submission, June 9 or 10, and so the decision was made not to send the report forward. Is that correct, because of this submission? You hadn't looked at the material.

A. I don't know if you would call it a decision, but—yes, yes.

Q. Were the materials from Senator Heinz reviewed and was anything learned from them that was found to be significant or important to the assessment?

A. If I recall, most of the material were memos, letters back and forth, type of information, and possibly other information dealing with the hearing. That is what I recall most of the material that was submitted contained.

Q. Would it surprise you to know that much, if not most of the material submitted by Senator Heinz on June 9, was the same material that you and Dr. Carter and Dr. Handelsman sat here and reviewed on April 17? Would that surprise you?

A. No.

Q. Then if you already had most of it in the month of April, why then would the assessment have to be delayed, because you had already seen it and you had asked for copies? Can you explain that?

A. First of all, I am not sure I understand what you are asking. You say when we were here at the earlier meeting we saw some material——

Q. That is correct, and much, if not most, of that material that you reviewed was in the packet of documents that was sent to you on June 9 by Senator Heinz. So in fact you had already reviewed most of that, had you not? Do you recall? Do you recall running into duplicates and things like that?

A. I recall going through the material and could not know what was in the packet until thoroughly going through it. I recall going through the material that you provided on June 9. I really don't recall whether some of it or all of it or most of it was what you either showed us or provided to us in your office at the earlier meeting. Much of that material, to my recollection, dealt with memos and letters, more like history of this issue, again, something else that I tried not to—a personal decision that might take me away from the scope that had been developed for this document. So it was material that I looked at and does not include.

Q. When did you first become aware of the infection outbreaks in the dialysis centers in California, Texas, Ohio, and from whom did you come to learn about these outbreaks?

A. Is that the ones associated with RenNew-D?

Q. These were in clinics in these States that involved at least two alternative chemicals to formaldehyde and were discovered during the months of April, May, June, and July of this year. When did you first hear about these infection outbreaks? California came first.

A. There were a number of outbreaks, and a number of sources of information. I find it hard to identify the source with the outbreak.

Q. Well, approximately when?

A. This committee informed us of outbreaks. Whether or not that was before or after we heard from FDA—Dr. Carter was in touch with people at FDA. Dr. Benson, I believe, provided us at one time with a memo regarding—a summary of some outbreaks. At one time it is possible CDC provided us—he was in touch with people also. He was involved to this to a great extent, Dr. Carter was, so he might have walked in, and in fact many times probably did, and tell me that he had learned, via the FDA, or the CDC, that they were investigating an outbreak, some of which were mentioned in the report.

Q. Do you recall Dr. Marshall or Dr. Carter having come to you on or about June 9, that was the same day of our submission, Senator Heinz's submission, do you remember them remarking to you that I had informed Dr. Marshall of the infection outbreaks and that he had not known of these outbreaks until my phone call? Do you recall that?

A. I don't recall that.

Q. FDA and CDC internal documents indicate that these infection outbreaks were discovered beginning in early April of this year. From your review of these documents, is that your understanding, early April, late March?

A. If you say—that is possible. I don't recall the exact timeframe. There were many outbreaks. They occurred in different months. If you have access to that, I will accept that as the timeframe.

Q. The reason why I ask you that is simply because, as you know, the vast majority of the documentation received by NCHSR from CDC and FDA didn't arrive until August 11. Isn't that correct? That is what your records show?

A. Then that is correct, and any information regarding those outbreaks, if they had come while—in the process of the report, early enough to incorporate it, would have been incorporated, as was the information from the MMWR, that was published on June 27.

Q. June 27?

A. The MMWR article published by the CDC?

Q. Yes.

A. So that information was put into the report because it was available, and I believe we had learned about outbreaks as we were—I think they were in the process of being investigated as the report was being completed to send to Dr. Windom so we put in a statement that such outbreaks had occurred and they were—I think we might have mentioned the disinfectant and mentioned that investigations were on-going.

Q. But the fact is, correct me if I am wrong, the vast majority of the documentation, the reports and memos generated by Dr. Murphy at CDC and FDA didn't reach your desk until August 11. Isn't that correct?

A. We received a lot of material on August 11, much of which was FDA investigations of dialysis facilities.

Q. And CDC. Isn't that right? The documentation that you received—isn't it a fact that the documentation you did receive from CDC was xerox copies of what this committee had received from CDC?

A. Ask your question again?

Q. Isn't it the case on August 11 you received two parcels of documents, one from FDA, and one from CDC, both of which had already been supplied to this committee on earlier days? Isn't that a fact?

A. That is a little different than the question you asked just before that. We did receive material—copies of material that went to this committee from CDC and FDA on August 11, that is correct. The FDA material included reports of investigations or medical device reports and other reports. The CDC material I am not that familiar with.

Q. You haven't reviewed it?

A. No.

Q. Why not?

A. Because by August 11 this thing had become very complicated and I am waiting for directions as to where we are going to go with this entire matter.

Q. So since August 11 you busied yourself with other tasks and responsibilities simply because you have not received any guidance, is that correct, on which way you are to go?

A. I think that the staff of the Senate Committee has kept us very busy trying to determine when things came in and who provided what on what date and recalling certain meetings and that has busied us a great deal.

Q. Isn't it the case that the very documents I speak of were two parcels of documents you received on the 11th, and isn't it the case that each and everyone of those documents is date stamped August 11?

A. Yes; we received documents on that date, yes, sir.

Q. And every one of those documents is date stamped, isn't that right? Someone laboriously went to each document and did this?

A. Yes.

Q. So you would know when you received those documents?

A. Yes; because it became important to know when the documents were received——

Q. Why was it important?

A. I do recall starting to go through CDC work——yes. Much of it seemed to be one of the investigators personal notes——

Q. And memos?

A. And I just skimmed through that. I don't know what was in that.

Q. Why was it so important for you to determine when you received these materials? Why was that so important?

A. Because your group had indicated that we are not receiving all the material that was available.

Q. Wasn't that the case?

A. We received material from FDA, as you just indicated, on August 11. We have received—material from FDA all along, but, yes, it is the case that we have material from FDA that was not provided earlier.

Q. A substantial amount, isn't that right?

A. That is hard to say. A lot of it is different groups commenting on the same outbreak. I am not sure what you mean by substantial. But it indicates--there are a number of reports that are involved.

Q. Did there come a time during the conduct of the assessment when you and Dr. Carter discussed the level of cooperation and response from FDA, CDC, and NIH in providing NCHSR documentation and material essential to the assessment?

A. Yes.

Q. Please relate for us that discussion or discussions and approximataely when they might have happened.

A. In the course of our assessment we send out memos to the agencies, and we did so in this assessment. We sent a memo to FDA, one to NIH and one to CDC. I don't recall exactly when responses to those memos were received but I was disappointed in those responses in general from those agencies, that they didn't contain more information.

Q. Let me share with you a May 28, 1986 memo to Dr. Carter from Dr. Robert Veiga, from the Office of Health Affairs at FDA. Do you recall having seen this memo at the time it was received by Dr. Carter?

A. Yes.

Q. Did this cause you, as you put it a moment ago, disappointment?

A. Yes.

Q. This memo reponds to Dr. Carter's request of April 9 to the FDA for information and data pertaining to dialysis device reuse, does it not?

A. It does.

Q. Dr. Veiga's May 28 response to Dr. Carter states, "All information concerning the issue of reuse of hemodialyzers, blood lines, tranducer filters and dialyzer caps is already available to NCHSR as part of the package prepared for the Senator Heinz hearing. The Office of Device Evaulation has no additional information."

Didn't you know at that time that this was not a true statement? Didn't you know that?

A. I am trying to recall what my response was on the day I received this. I don't think I reacted to that part of the memo about no—has no additional information. I was disappointed that they did not address the questions more specifically that we sent them in the memo in getting definitive answers to them. You made your question specifically to at that time.

Q. Yes; at that time. Didn't you know by May 28 that indeed these agencies, at least with regard to FDA, was not sending you everything? You had already come here on April 17. You had looked at what we had. By May 28 the infection outbreaks had already begun. Investigations by FDA and CDC stated on May 9, May 10. Isn't that why it disappointed you?

A. No, sir; I already stated that what disappointed me was that our memo to the FDA reiterated the questions that we presented in the Federal Register notice and I was disappointed that they did not, and that was their choosing, did not respond more directly to the questions in the memo to the FDA. That was why I was disappointed.

Anything that we requested of the FDA they provided. So that had I known that something was available, I would have requested it and based on my experience with the FDA, they would provide it. There was a time when I was requesting material—or I should say final reports—reports of the outbreaks and I was told, and I don't recall exactly when and whether this was before or after the date you are talking about, but when they would be available I would get them. If that is what you are referring to, then I requested it and did not get it. We were aware there were outbreaks. The people had to go out there and investigate the facilities——

Q. Mr. Erlichman, didn't there come a time when you knew that this statement in this memo was not a true statement?

A. You changed your question.

Q. Now I am taking you past that time, Mr. Erlichman, and I am asking you did there come a time when you came to realize that this was not a true statement and when was that time?

A. I don't believe that the copies of the FDA investigations of problems in the dialysis facilities were part of the package prepared for the Heinz hearing, for the Senator's hearing. If that is the case, then there was a time where we were aware that there was additional information that we did not have, which you referred to earlier.

Q. Was it in June that you came to realize that this statement was untrue, or was it in July? When was it, Mr. Erlichman?

A. Again, I think I can best answer that by saying that if I realized that there was material available, I would request it. I was often in touch with Bob Eccleston at the FDA and at no time did I request something that he did not send if he felt that it was ready to be distributed by the FDA.

Q. To be distributed to whom?

A. So that at what specific time I became aware, I don't recall. If you want to—you kept providing things and—if it was before the report went to Dr. Marshall, I would have requested it and would have included it in the report. So that based on that, I would say that I became aware of some of these things after it was too late to incorporate into the report.

Q. Isn't it the case, Mr. Erlichman, that on June 9, or soon thereafter, after you had reviewed the comments and a substantial amount of documents submitted to NCHSR by Senator Heinz, many of those documents dated months prior to that, never having been shared with NCHSR by FDA or any of the other agencies—didn't you become aware after looking at that submission by Senator Heinz dated June 9, that that statement in that May 28 memo from FDA, was untrue? Isn't that when you came to learn that this was not a true statement, simply because Senator Heinz had provided you with documents that they had not provided to you. Isn't that the case?

A. Can you be more specific as to what documents you are talking about. Are they the same documents we received——

Q. The documents are documents that were shared with you on June 9 that were sent to you by Senator Heinz in response to your Federal Register notice for comment.

A. I realize what you are referring to. I don't recall what specific document—what specific memo, letter——

Q. Would you like to go through the collection of documents to determine whether or not after reviewing them in June that you knew this was not a true statement?

A. I would like to see those documents that you are referring to. [Pause.]

Mr. Michie. We will take a short recess while we retrieve those documents. [A recess was taken.]

By Mr. Michie.

Q. Do you recognize that collection of documents as those having been sent to NCHSR?

A. I will take your word that these are the same documents that were delivered.

Q. Are you familiar with—are you acquainted the July 8, 1986 memo that was written by Dr. Marshall and presented to Dr. Windom on that same date at a meeting? Are you familiar with that document?

A. I am. I became familiar with that document when you showed it to me in Dr. Carter's office after that date and we discussed it at the earlier deposition.

Q. I am going to read to you from the last page, page 3, of that memo. Do we have a copy for the witness?

From Dr. Marshall's memo dated July 8, 1986, the second to last paragraph on page 3, second to last paragraph:

> After the hearing Dr. Macdonald directed me to carry out an assessment of dialyzer reuse. In the course of carrying out that assessment it has become evident that communication within the Public Health Service is less than adequate. We uncovered serious omissions and inaccuracies in the testimony which had been prepared based on facts made available last March. Some of these only came to light the day before the comment period for the assessment expired when we received several hundred pages of information from Senator Heinz. Included in that were internal PHS documents that had not previously been shared with us. On the strength of that, I requested an extension of July 10 for completing the report.

Does that not refresh your memory to the fact that as of June 9, or soon thereafter, and I am assuming that Dr. Marshall relied upon your review of those documents, that the May 28 memo you received from Dr. Veiga, was in fact not a true statement?

Does that refresh your memory, Mr. Erlichman?

A. You are still looking for a date that I realized that we realized we did not receive all of the material. I am still trying to determine if such a date is possible.

We met with Dr. Marshall the morning of the July 8 meeting——

Q. You were present at that meeting?

A. Dr. Carter and I met with Dr. Marshall. In fact, at the time—at that time I don't think I knew there was going to be a meeting in Dr. Windom's office later that day. In fact I had no way of getting home that night because I didn't drive, which I would have done if I knew there was a meeting. So this memo, which I had not seen until you were at our office—if you could tell me the date of that.

Q. I think that was around August wasn't it?

A. I will accept that. Until August 14 I had not seen this memo. When I saw this memo I was trying to understand what Dr. Marshall was referring to and I believe that Dr. Carter indicated things—it would be better to ask Dr. Marshall and Dr. Carter.

Q. What I am asking you——

A. But I believe that the omission, since I saw this—I didn't see this until August, I assume the omissions—and I thought I would look through that material you provided on the 9th or 10th, dealt with communications. So Dr. Carter looked through that and I imagine indicated to Dr. Marshall that there might have been communications by the agencies that might not have been provided.

In terms of inaccuracy, I am not sure what he is referring to.

Q. If you will read that second to last paragraph, Mr. Erlichman, I think you will find that Dr. Marshall is quite clear on his statement, there is no qualification there. He said some of these only came to light the day before the comment period for the assessment expired and that was June the 9th, when we received several hundred pages of information from Senator Heinz. Those are the records we presented to you a moment ago. Dr. Marshall's July 8 memo stated: "Included in that were internal PHS documents that had not previously been shared with us."

Now I am assuming that he was relying upon your review of those documents or did Dr. Marshall review that stack of documents in order to reach that conclusion? Can you tell us?

A. For a clear and definitive answer you should ask Dr. Marshall since he made this statement, what he is referring to. If I indicated to Dr. Marshall that we had not received something, there might have been one or two reports that we didn't receive and when I found out about them—and I am referring to something that is not necessarily in the package that you delivered to our office on June 9, but if I agreed with him that there was some material that we did not have that we received later when we found out about it, it might have included a draft copy of a report dealing with formaldehyde toxicity and dialyzer reuse that came to my attention but it is not—the report has not been completed, but when we requested it, it was sent. That might have been something I indicated we received afterwards. There was another document, again, a draft from the FDA——

Q. Are these documents you speak of in that stack there?

A. I don't believe so, but I found out about these documents on my own in talking with people at FDA and I asked them to send it. Your question is referring to Dr. Marshall's statement——

Q. I am asking you, did you review that stack for him?

A. I reviewed that to see what I wanted to incorporate into the assessment, and I don't believe I saw material, like investigations, that should be included in the assessment or else I would have included them in to the assessment. I told you that Dr. Carter might have seem memos and other material that had been generated earlier that was not provided and that he might have made some comments.

You have to understand, as you indicated earlier, Dr. Marshall was very involved in this work and so was Dr. Carter, so this information could have come from myself or Dr. Carter. I did not provide Dr. Marshall, I don't believe, with any statement that indicated inaccuracy in his testimony. This was the first time, when I read the memo, that I was aware of such a statement.

Q. Now I think we are clear. What you are saying is Dr. Marshall may very well have gotten that information that he put into that memo from Dr. Carter and he was relying upon Carter, and Dr. Carter is the person who may have identified for him the documents within that stack that is sitting over there that had not been shared with NCHSR by PHS. Isn't that correct?

A. When I reviewed the stack of material I reviewed it with the intent——

Q. Answer my question, please.

A. I am answering the question. I reviewed the material with the intent of finding material that should be incorporated into the report. I was not reviewing with the intent of whether or not somebody else had sent us the same memo and when the memo was dated and whether we received it for the testimony.

Q. All I am asking, Mr. Erlichman, is it possible that Dr. Marshall relied upon Dr. Carter for that bit of information? Isn't that possible?

A. Yes; it is possible.

Q. And you are stating it did not come from you. Is that correct?

A. I though I clarified it but I will try again.

Q. Is that correct, did you not say it did not come from you?

A. I don't believe I made any statements to Dr. Marshall—may I answer the question?

Q. Please.

A. I don't believe I made any statements to Dr. Marshall indicating I had information that indicated he had made inaccuracy in his testimony.

Q. We are not talking about the testimony.

A. I might have said we had a report or two from FDA—well, this is saying—that is my——

Q. Let's go on to the next question, if you are finished.

When did you become aware of the existence of the FDA's Reuse Committee?

Mr. RISEBERG. Does FDA have a Reuse Committee?

The WITNESS. I am aware that FDA has a Reuse Committee. I am aware they made reports.

By Mr. MICHIE.

Q. It was during the course of the assessment?

A. Yes; it was.

Q. Do you know what the function of the Reuse Committee is? Do you understand that? Very briefly what is your impression of the Reuse Committee?

A. My impression is that the reuse of medical devices is an issue and the FDA is aware of that and formed a reuse committee. I am not exactly sure when, to deal with that. Dialyzer reuse comes under that and they have been dealing with that issue as well. They have been meeting and generating material. Lately they have been responding to dialyzer reuse and the comments of the committee.

Q. Are you aware that the FDA had functioning a second committee, the Dialysis Use Committee concurrently with the Use Committee? Are you aware of that?

A. I don't think so. The dialysis——

Q. The Dialysis Use Committee as opposed to the Use Committee?

A. I don't believe so. When was it formed?

Q. I believe it was formed, sometime, according to FDA, sometime in 1983 or 1984, around the same time as the Use Committee.

A. I don't believe so

Q. Let me share with you a copy of the October 23, 1984, report of the Dialysis Use Committee. You will note that his report addresses several issues concerning hemodialysis, including reuse. In fact, on the first page of the report——

A. May I please have a moment to become familar with this?

Q. Please.

[Pause.]

Q. If you will note on the first page, second paragraph, reuse is listed as one of a number of issues considered by FDA to be of an urgent, that is the word used in there, urgent nature at this time—at that time.

Mr. RISENBERG. Is this underscoring part of the original report? Dialyzer reuse is underscored.

Mr. MICHIE. This is as it was received from this committee from the FDA.

The WITNESS. Since you are reading from this, and interpreting it and make a point of urgent issues, would you care to tell me what that means to you?

By Mr. MICHIE.

Q. Do you know the definition of urgent, Mr. Erlichman?

A. I have never used it as urgent issues.

Q. Isn't that what it states in there?

A. What is your question?

Q. Why don't you read the sentence wherein that word is used?

A. As a result of a number of urgent issues on hemodialysis, dialyzer reuse, and first-use syndrome, the Director of the Office of Compliance at the November 28, 1986, meeting agreed not to promote the safety and effectiveness of hemodialyzers.

Q. Thank you.

Had you seen this report prior to your appearance here today?

A. I don't believe so.

Q. Attached to this 3 page report are 39 pages of user related problems and elaborations including bacterial contamination, inadequate disinfection procedures, toxic materials from the water supply crossing into the bloodstream of patients and others.

My question to you is, Might you not have been interested in this particular report had it been provided to you by the FDA?

A. I was interested in any material regarding reuse and the issues that we were trying to deal with. Just going through this quickly, it seems that not everything in here might pertain but if there is material on reuse, and it identifies reuse, I would be interested.

Q. Would you like to have a copy?

A. Certainly.

Q. We will be happy to provide.

I have a June 25, 1986, memo to Dr. Marshall from Jim Benson, Deputy Director of the FDA Center for Devices and Radiological Health.

Have you seen this memo?

A. I believe I did, yes.

Q. Soon after it was received?

A. Probably.

Q. To your knowledge, was this the first notice to NCHSR from FDA regarding the infection outbreaks?

A. Written notice?

Q. Which ever term you wish to use.

A. We probably knew about this by phone before we received the memo, but I can't be certain. If there were earlier written memos, they would be in our files. If this is the one that your are presenting, it is probably the only one——

Q. May I make a suggestion? May I suggest when you return to your office tomorrow or sometime in the near future that you check your files and as a courtesy to the chairman of the committee you inform us whether or not there are earlier memos notifying your agency of these outbreaks? Would you do that?

A. All the memos that we have received were provided to you in your——

Q. You are incorrect on that, Mr. Erlichman.

A. I am?

Q. Yes, you are.

A. I don't believe I am in the sense that the memos I am aware of that I had in my possession when I was told to provide the staff of the subcommittee with our information——

Q. We still do not have the memos.

A. I thought we provided.

Q. You did provide them. You did so provide them to the Department, but the Department has yet to provide them to us.

Mr. Riseberg. Why don't we have you direct a request for any further documents to Mr. Docksai.

Mr. Michie. We have done that repeatedly over the last 2 weeks.

By Mr. Michie.

Q. At about that same time, during the week of June 22, CDC was in the process of drafting an article for its June 27 edition of the MMWR. Did you become involved during that week in discussions with Dr. Marshall or with anyone at CDC or FDA regarding the content of that article?

A. I was aware that the MMWR was coming out and that it was being prepared and I think it was being prepared by CDC and or with input from FDA.

Q. Did you offer any input with regard to the content of this article?

A. I was not part of the team that performed the investigation. I was not part of any group in OHTA—I was not involved in preparing the MMWR.

Q. Did you never speak to Dr. Murphy, Dr. Solomon, and Dr. Matone at CDC about this material prior to its publication?

A. It is possible I did.

Q. What would you have discussed with them with regard to the content of this article?

A. The MMWR was very clear and had a lot of information, so it provided me with enough information to incorporate those findings into the assessment. One of the issues was that in one of the facilities there was a death and I think that—I don't know if that was before the MMWR came out, it could have been after. But if I had discussions with Dr. Murphy, which I did, and with Dr. Solomon, which I did, it was in that regard.

Q. What about with FDA, did you have discussions prior to publication, with Nurse Reid, Dr. Villarroel, Mr. Eccleston, or Mr. Benson?

A. I had a conversation with at least one of those persons. Bob Eccleston, I believe.

Q. Prior to publication?

A. Prior to publication—may be it was from him that I found out that the MMWR was coming out on that subject matter. Indicating that the MMWR was going to be published on June 27 and that he referred to the conclusion or recommendation in the MMWR which he thought contradicted or——

Q. Wasn't in line with?

A. Was not in line with earlier PHS feelings on the need for clinical trails.

Q. Especially the testimony that was given on March 6 by Dr. Marshall. Isn't that correct?

A. That is part of the earlier PHS position.

Q. But that position and policy was stated at the hearing, wasn't it?

A. I believe so.

Q. And so Mr. Eccleston was concerned about this article mentioning the need for clinical trials. Is that correct?

A. I believe that the FDA and CDC were, as I said—either CDC was writing up the MMWR with input and comments from FDA. That was my understanding. I really didn't have much information about it. In that regard, as the development of any report, there are probably different ways of expressing things and I think what Bob was saying is they were in discussions with CDC over the final version of that report. I think you will see, as you have been interested in drafts, that reports go through many drafts and I think he was just indicating that they were still discussing the final version. That is the extent of my information.

Q. Isn't it the case that Mr. Eccleston expressed a preference to you that this article should not call for clinical trials, especially controlled clinical trials?

A. He might have. It was my feeling that this dealt with RenNew-D and was wondering whether or not one could generalize to facilities that used formaldehyde as a disinfectant. So I was personally not sure—it didn't matter, I had no input to this, but this was just my feeling, and I expressed it to Bob Eccleston, whether or not one could make this recommendation based on that incident regarding RenNew-D for reuse. You might make it based on other information, but at that point in time this incident was involved with a disinfectant that is used in a small percentage of the dialysis facilities.

Q. Wasn't there a bit of irony in this in that the CDC had perhaps a year or two ago begun to recommend to these clinics that they get away from formaldehyde and use alternative chemicals? Wasn't that the irony?

A. If you could share that, the CDC statement to get away from formaldehyde.

Q. Your are not aware of CDC encouraging the dialysis community to go to alternative chemicals?

A. I think in general people involved in this issue would like facilities not to use formaldehyde. However, it seemed that it is difficult because 85 percent of the facilities still use it. So they would not be the only ones indicating it would be nice. Possibly you see what happens when you try to get away from formaldehyde, you might have problems.

Q. Did Dr. Marshall share with you the contents of his discussions with CDC regarding the article?

A. I don't believe so.

Q. Do you have a definite recollection that he didn't?

A. No.

Q. Is it that you don't recall—he might have, but you don't recall?

A. I said I don't believe I recall him discussing his comments with CDC. I do know that he probably was called by Bob Eccleston to discuss it but I really don't have any other information.

Q. Moving forward in time to July 8, 1986, are you aware that Dr. Carter and Dr. Marshall met that morning to discuss the progress and status of the assessement? You must be aware of it. I think you told us a little earlier that you were there. Isn't that correct?

A. I was at a meeting that morning. May be there was more than one. Becasue at that meeting I thought that we were dealing with trying to get more input from, I thought, it was my impression, that we were trying to——

Q. To get a better response?

A. To get a better response—thank you, that was a good comment. A better response from the agencies——

Q. In providing——

A. Better response from the agencies in regard to the issues we were dealing with.

Q. And in providing documentation?

A. Getting a better response from the agencies.

Q. Wouldn't that include documentation?

A. It would include anything that would include information on the matter.

Q. Now did I understand you correctly that earlier you stated you did attend a meeting at which Dr. Windom was present along with Dr. Marshall and others?

A. You are correct in remembering that I stated that, yes.

Q. Were you there during the whole meeting?

A. No.

Q. How long were you there?

A. Dr. Carter and I arrived later, may be ten or 15 minutes after the meeting had started.

Q. When did Dr. Marshall arrive?

A. He was already there.

Q. During the time that you were at the meeting did Dr. Marshall present to those in attendence that July 8 memo that we referred to earlier?

A. The memo had already been presented. It was either in front of somebody or in their possession.

Q. Did you get a copy?

A. No, I did not, otherwise I would not have indicated that I had not seen it until you had shown it to me.

Q. Do you recall at any time during that meeting anyone in that meeting criticizing, scolding, or admonishing Dr. Marshall for having written that memo in the first place? Do you recall that?

A. There was a comment by one of the attendees, I am really not sure who that was, that he might not want to have this memo go forward.

Q. Might not?

A. I don't know if it was an order by that person. It might have been a suggestion. It wasn't Dr. Windom who made that statement. Dr. Marshall indicated that he would collect the memos at the end of the meeting.

Q. Didn't this person also suggest to Dr. Marshall that he in fact retrieve all copies and get rid of them?

A. He said something in that line, yes, or retrieve them, I guess for the purpose of disposing of them.

Q. To dispose of them?

A. I don't recall that he said that. Somebody suggested they be collected. If it was for the purpose of disposing them, I don't recall if that person used those words.

Q. You don't recall but it is possible those words were used?

A. Anything is possible, yes, sir.

Q. Do you recall Dr. Windom having a copy of that memo before him?

A. I would assume that since Dr. Windom in his position was attending that meeting, was presiding over that meeting, and when Dr. Marshall distributed the memo, I would imagine that Dr. Windom might have received a copy. I really don't know. I wasn't there.

Q. But you were there when all of the copies were gathered up and given to Dr. Marshall?

A. No. We got up and left and I really don't know whether he stood at the door or he went around or people left them. Obviously not everybody turned them in because I believe you had a copy of that memo.

Q. So you left before. Dr. Marshall did, you left the meeting before Dr. Marshall did?

A. No, no. When the meeting ended, we left. I don't know the process that was carried out to get the memos that were distributed.

Q. You don't remember everyone around the table handing their memos to Dr. Marshall?

A. When the meeting broke up there was individual discussion. There were people there from CDC, everyone there with personal information on reuse. There was a lot of discussion. I don't recall an official process of collecting the memos.

Q. Getting back to the failure of FDA and CDC to provide NCHSR in a timely manner documents pertinent to the assessment, I think as we established earlier, according to your records it wasn't until August 11, 5 days after the assessment report was sent forward to Dr. Windom, that these agencies had finally begun to provide NCHSR the vast majority of these materials. Isn't that correct?

A. For the record, could you mention two or three of the CDC reports that you are referring to that were not provided?

Q. Would you like to have the entire collection here before you on the table?

A. I believe you indicated that I have that in my office or one of my offices, that was received on August 11.

Q. That is correct.

A. But you couldn't give me an idea other than Dr. Murphy and the other people there, their notes—I am curious as to the CDC reports you are referring to.

Q. I think what you should do, if I may make this suggestion, you should go back and review these materials. I think we are in agreement that we are talking about the same materials, materials that you received, that NCHSR received, from CDC, Xerox copies of materials they provided to us several days earlier, and the date on that material is August 11. Isn't that correct?

A. That is correct. I thought it would be helpful, since you keep referring back to the CDC reports—I was just curious——

Q. I said documents, not reports.

A. That clarifies it. Thank you.

Q. Now I will give you one example of a document that you obviously didn't receive in a timely manner. For example, on page 54 of the assessment report, and we have a copy here for your reference, there is a finding and conclusion, number three, which addresses CFR provisions governing——

A. Excuse me. Wait a minute. Can you start that again? Page 54?

Q. And in the assessment report there is a finding and conclusion Roman numeral No. III. Do you see it there?

A. Yes.

Q. Which addresses 21 CFR, the provisions governing the Government's regulation of medical device reprocessers. Is that correct?

A. Yes.

Q. On page 55, if you turn to page 55, there is the statement, "It is unclear whether good manufacturing practices could be required pursuant to 21 CFR 807.65(d)."

What was the basis for this statement in the report, Mr. Erlichman?

A. I think it is important at this time, since we will be discussing these conclusions and findings, at great length and the recommendations and the conclusions and findings, the primary author is Dr. Carter with input from myself, but I believe he said, therefore, and he was referring to the two previous citations on page 54, indicating that while 21 CFR 820.3(k) defines a manufacturer as any person—et cetera, 21 CFR 807.20(a)(3) states that individuals who repackage or relabel a device are required to register as manufacturers.

He indicates, on the other hand, 21 CFR 807.65(d) exempts licensed practitioner, including physicians, dentists, et cetera. That is the basis for his—I believe was the basis for his statement, since it preceded it. Therefore, it is unclear whether good manufacturing practices could be required pursuant to 21 CFR 807.65(d). Therefore, in light of that, our recommendations——

Q. I don't think it is necessary we go into your recommendations. All I am asking you is was there——

A. Let me just complete it. Our recommendations to Dr. Marshall indicated that we thought a policy definition may be appropriate——

Q. A policy definition, yes. I am listening.

A. We indicated to Dr. Marshall in our recommendations that we thought a policy definition may be approriate in the area of GMP versus voluntary standards and should address the manufacture and look at the status of existing and other guidelines and we felt that the agency responsible for this would be FDA.

Q. Let me share with you now a copy of an April 16, 1986, memo to Secretary Bowen from the then Acting Assistant Secretary for Health, Dr. Donald Macdonald.

A. Dr. Macdonald states, "FDA's general counsel has concluded that a legal argument can be made either way for imposing GMPs or not."

Attached to this memo you will find a briefing paper entitled hemo dialysis.

Please take note of the short paragraph on page 1 with the heading "concerns." It states, "general counsel says a legal argument can be made for imposing GMP's or not enforcing them on dialysis clinics. It therefore becomes a policy decision."

Were you aware of this memo and opinion of the general counsel prior to completing the assessment report, because, doesn't this address the very thing as in your recommendation, there is a need for a policy determination, when in fact that particular thing was made back in April—were you aware of this memo and opinion of the general counsel prior to the assessment report?

A. I have seen this memo. I am not sure if it was before or after the assessment went to Dr. Windom, but I felt, without seeing this memo, that is seemed to be a policy decision, personally, which certainly bears no weight since, as you can see, general counsel is involved in this. We addressed it in the assessment by indicating what is stated in the CFR and felt that FDA needed to deal with this.

Q. Are you familiar with the Febraury 24 working paper, FDA's working paper, Policy Considerations for the Processing of Devices? Have you seen that?

A. At one time or another I have seen some or all, I think there were three various—some are called working papers, some have other names, that the committee has produced, a couple of reports——

Q. Let me refresh your memory.

A. And I have probably seen some of what is written in them.

Q. On the first page of this February 24 working paper, which, incidentally, is not marked draft, it states, "the Reuse Committee believes that FDA has the authority under the existing law to regulate processing of devices for reuse whether it is carried out by the original manufacturers, health professionals or others."

A. Can you repeat that, please?

Q. I would be happy to. "The Reuse Committee believes that FDA has the authority under the existing law to regulate processing of devices for reuse whether it is carried out by the original manufacturers, health professionals or others."

Now what I don't understand is why didn't you state in the report the fact that in April of this year and in February of this year the FDA stated quite clearly, based upon an opinion from its own general counsel that it was a policy decision that would have to be made and that so, therefore, there were no legal problems? I am wondering, why didn't you state that in your report?

A. What you are indicating is that a great deal of time and effort has been made by FDA addressing this issue. I don't believe that we had received any definitive statement by the FDA regarding this issue. If we had, or I was aware of such, I think I would have incorporated it into the report. That is way we made the recommendation that we did.

Q. I have here for your reference a copy of Dr. Marshall's August 6 cover memo under which Dr. Marshall transmitted the assessment report. I also have here for your reference a copy of the August 11 cover memo, that is August 11 cover memo for Dr. Windom's signature under which he transmitted the assessment report to Dr. William Roper, HCFA Administrator.

Both memos are only one page in length but there are statements in Dr. Windom's statement to Dr. Roper that do not appear in Dr. Marshall's memo. For example, in the second paragraph of Dr. Windom's memo, "The findings to date indicate when physicians facilities exercise appropriate quality control over reprocessing of dialyzers," and I will skip a few words, beginning again, "patient outcomes appear to be no different in facilities that reuse dialyzers than for those facilities where single use is the normal operating mode."

Now is this statement included in Dr. Marshall's August 6 memo to Dr. Windom? Do you find that statement anywhere in there?

A. I don't believe that statement is in Dr. Marshall's memo.

Q. Can you show us where this statement can be found in the findings and conclusions of the assessment report itself? Can you show us that, findings and conclusions beginning on page 53?

A. Verbatim that is not in the findings and conclusions, but I don't—but Dr. Windom might have gone through various parts of it and put that together. You would have to address that together.

Q. Dr. Windom.

Can you explain why there is this difference between these two memos?

A. Certainly not, since Dr. Marshall wrote one memo and Dr. Windom the other and I was not involved in either memo.

Q. You were not—you didn't even get a chance to review the August 6 memo before it went out?

A. I don't believe I saw the August 6 memo until after it went out.

Q. Had you seen the August 11 memo prior to your appearance here today?

[Pause.]

Q. Do you recall seeing them?

A. I have seen so many memos and the comments are very similar. It is possible I saw this before today, yes.

Q. You stated a moment ago that Dr. Windom wrote this August 11 memo to Dr. Roper. I would like to share with you what is called the control version and you will note that the names of drafters and revisers toward the bottom of the page and you will note that it was Dr. Marshall who drafted this memo. Isn't that correct? Isn't he listed as the preparer?

A. That is correct. And it was revised by a number of other people.

Q. I believe the total comes to 11 individuals, including Dr. Mason, Director of CDC, representatives of NIH, FDA, Office of the assistant Secretary for Health, and the Office of Chief Counsel, presumably PHS. Your name and that of Dr. Carter are missing. Does that mean that you and Dr. Carter, the two individuals the closest to the assessment, were not given the opportunity to review this memo in order to give advice and counsel on whether it was accurate? You have already answered the question with regard to yourself. Do you know if Dr. Carter was privy to this memo?

A. I wouldn't know that. I don't believe I know that.

Q. I note also that a D, initial D. Riseberg is listed among the revisers. Would that be you, Mr. Riseberg?

Mr. RISEBERG. It is not a common name.

Mr. MICHIE. Could you explain your role?

Mr. RISEBERG. I am not a witness before this committee.

Mr. MICHIE. At the beginning the session you were quite careful to point out that this was not a desposition, that it was an interview, voluntary and so on. What is your objection?

Mr. RISEBERG. As an attorney for the Public Health Service I am not prepared to provide any information today.

Mr. MICHIE. So you then would not care to describe for us your role in this?

Mr. RISEBERG. I am not prepared to, no.

Mr. MICHIE. Would you ever be prepared to?

Mr. RISEBERG. I am not prepared to deal with any substantive questions.

By Mr. MICHIE.

Q. Returning to the memo, it contains the statement, "The absence of reported increases in the morbidity and mortality given the increased use of reuse suggest that virtually all facilities are following adequate procedures."

Is this statement included in the August 6 cover memo to Dr. Windom from Dr. Marshall?

A. Would you try that again, please?

Q. The statement that I just read from the August 11 memo from Dr. Windom to Dr. Roper, do you find that statement in the August 6 memo written by Dr. Marshall to Dr. Windom?

A. I think you already asked that?

Q. No. This is a second statement. It is talking about—it says here——

A. Yes; which statement?

Q. "The absence of reported increases in the morbidity and mortality given increased practice of reuse suggest that virtually all facilities are following adequate procedures."

Now my question again is do you find that statement in Dr. Marshall's August 6 memo to Dr. Windom?

A. I do not.

Q. Can your show us where this statement is contained in the findings and conclusions of the assessment report itself, beginning on page 53? In the assessment report do you find that statement anywhere in the findings and conclusions?

A. In the report itself it indicates that there has been no reported increase in mortality. Some of the studies have indicated no increase in morbidity, but I don't believe the report indicates that all facilities are following adequate procedures.

Q. Virtually all facilities are following adequate procedures.

A. The report does not state that.

Q. Therefore, is that a true and accurate statement based upon the assessment findings?

A. I don't believe that I would write that based on the information I reviewed, that all facilities are following adequate procedures.

Q. Again, I will ask you, in your opinion, having been very closely involved in this assessment, do you consider that to be a true and accurate statement?

A. No; I do not. I think that one might want to modify that or say it in defferent terms based on the information.

Q. So your answer is no, it is not a true and accurate statement. Isn't that correct?

A. No; I said that I would not write that. I said they have concluded—they have taken the comment that the absence—they took something that was in the report—again, I am looking at this now and responding to this at this time. They have stated that the absence of reported increases in the morbidity and mortality given increased practice of reuse suggests that virtually all facilities are following adequate procedures. That was a conclusion based on what they said and found written elsewhere. They did not take that entire statement from the document. I would not write that statement. It doesn't make it a false statement even if I disagree with it.

Q. Mr. Erlichman, isn't it a fact that based upon your findings and upon a very inadequate and unvalidated data base taken from the CDC, from their annual survey, that there is no way anyone could draw the conclusion that virtually all facilities are following adequate procedures? Isn't that the case?

A. If we thought that was the case we would not have recommended standards for the facilities to follow in our recommendations.

Q. So, therefore, I ask you once again, is this a true and accurate statement or is it not?

A. I would not have made the conclusion that they made. I would disagree with it.

Q. So is your answer, yes, it is an inaccurate statement?

A. In my opinion I would not have come to the same conclusion that they did based on that information.

Q. Based on the information and on your findings again, please give me an answer yes or no, is this in your opinion a true and accurate statement?

A. No.

Q. Among the CDC documents that NCHSR did not receive until August 11, several days after Dr. Marshall had submitted the assessment report to Dr. Windom is a July 8, 1986 memo, and we will share that to you. This was addressed to Dr. James Hughes, Director of Hospital Infection Programs from Doctors Murphy and Solomon, both of whom are epidemiologists. [Eem.]

A. This is from who to who?

Q. The names don't appear on the memo but we have identified them——

A. Internal CDC memo?

Q. Yes; and you do have a copy back at your office. The memo is addressed to Dr. James Hughes, director of the CDC Hospital Infection Program from Doctors Murphy and Solomon, both of who are epidemiologists at CDC. Dr. Murphy is the epidemiologist who performed the survey at five clinics where infections began.

Please note on page two Doctors Murphy and Solomon state:

> It is evident that the data base concerning the safety and appropriateness of reusing disposable hemodialyzers is currently inadequate to make a scientific assessment of whether or not this practice should be promoted, tolerated or prohibited for public health purposes. Even if the practice itself is found to be safe or even beneficial, there is an obvious need for standards addressing the manner in which reuse is performed. Such standards must be based on clinical trials and incorporate long term assessments of patient outcomes using a variety of measures including morbidity and mortality. Although such studies may be outside the purview of CDC, we can contribute our epidemilogic expertise to the development of appropriate methodologies by developing model protocols to be tested in our studies of dialysis associated bacteriology.

Have you read this memo before your appearance here today?

A. I don't believe so.

Q. I mentioned you do have a copy.

A. In the material that came in in August?

Q. Yes, August 11. That is when you received it. [Pause.]

Mr. RISEBERG. While he is looking at it, perhaps we can discuss just how much longer we have?

Mr. MICHIE. I think we will be able to finish.

By Mr. MICHIE.

Q. Do you recall having discussed with Dr. Murphy or Dr. Solomon any of the information contained in the passage I just read to you?

A. In the conversations I might have had with people at CDC, they would pertain to formaldehyde in terms of the level—the percentage of disinfectant that area would be used was discussed, the death at the Dallas facility caused me to be in touch with them a number of times trying to get information on that——

Q. I understand, but do you recall this information specifically?

A. I am trying to—I don't have immediate recall.

Q. We are also trying to abide by your time constraints.

A. I realize that. Thank you.

I don't believe the initial comment about inadequate—the data base being inadequate to make a scientific assessment, or whether or not this practice should be promoted, I don't believe that was discussed or brought to my attention. What was brought to my attention by either Dr. Murphy or Dr. Solomon, I think, was the need for more surveillance or better CDC surveillance, or better surveillance at the facilities for picking up infections, and in fact, our recommendations addresses some of his concerns.

Q. But if this had been brought to your attention, isn't it likely that you certainly would have note of it, and perhaps even incorporated this into your report? This to me is a fairly strong statement, "the data base concerning the safety and appropriateness of reusing disposable hemodialyzers is currently inadequate to make a scientific assessment of whether or not this practice should be promoted, tolerated or prohibited for public health purposes. Even if the practice itself is found to be safe or even beneficial, there is an obvious need for standards addressing the manner in which reuse is performed."

Would not that have been germane to your assessment and to your report?

A. Our findings and conclusions and recommendations agree with much of what is said here but not all, based on our review. We certainly agree 100 percent that standards are necessary and recommend those.

Q. Standards or guidelines? I ask that simply because people sometimes confuse those two words. Standards as you know, standards in the sense of being standards being promulgated by FDA or CDC are enforceable and guidelines ae not enforceable and that is what exists now in clinics, does it not?

A. It was our intent that it was something that came through the FDA, that it was something more than guidelines that could or could not be followed or didn't have to be followed.

Q. Guidelines?

A. There are guidelines available today to any facility; many guidelines.

Q. Do any of them cover bloodlines, transducer filters or blood caps? Do the AAMI standards cover those devices?

A. Can I——

Q. Please, go ahead.

A. I would like to finish answering, because you felt this statement was critical or important. Our first recommendation is standardize—including many areas and FDA as well as CDC should address those. As I said, we came to similar conclusions. Also, for the need for standards. He also indicates there should be clinical trials. We indicate that additional information is necessary. There is a lack of information and that additional studies should be done.

Q. Why didn't you use the term clinical trials, controlled clinical study; why didn't you use that?

A. In our recommendations we indicated that studies are needed to determine if the reuse of hemodialyzers is safe when compared to single use and compared disadvantages associated with this——

Q. Mr. Erlichman, studies can cover a broad spectrum of material, protocols and whatever. That doesn't necessarily mean controlled clinical study. You are aware of that, are you not?

A. In our findings and conclusions we indicate that no adequate clinical trials have been performed to address either the short- or long-term safety and efficacy of the practice of single versus multiple use of the hemodialyzers and the other components.

Q. But do you recommend controlled clinical trials; is that in your recommendations? Although you state they have not been used, have you recommended them?

A. We indicated the need for studies.

Q. Not controlled clinical study but just studies?

A. Studies obviously include clinical trials——

Q. Could include?

A. Certainly. I think it would be up to the people who are experienced and knowledgeable in this area to determine what studies would be most appropriate in obtaining additional information regarding the safety and efficacy of reuse. I think it is important to understand that there is information, some of the studies that have been cited in the report, that did not show an association between reuse and morbidity and mortality. They are certainly not clinical trials.

Q. Why then is the CDC recommending——

A. So I would more agree with the statement that Dr. Marshall made to Dr. Windom that while the current information does not provide evidence that multiple use is without hazard, neither did it constitute sufficient base to abandon reuse. I believe we would differ with Dr. Murphy on that.

Q. But you said a moment ago you didn't discuss this inadequate data base, you didn't discuss with them the fact that they feel their own data base is so inadequate that they can't even make a judgment on whether or not reuse is safe and that is what that memo says, doesn't it?

A. I don't believe they brought it to my attention for discussion.

Q. Don't you think that such a discussion——

A. That comment was not made in the CDC memo to us.

Q. Don't you think that that discussion certainly would have been germane to your assessment had you had the discussion during the assessment?

A. If people at CDC had comments to make, we certainly would have sat down and listened to them and discussed it with them.

Q. And therefore it would have been germane, isn't that correct, to have a discussion about——

A. Data base to the topic is certainly germane.

Q. Are you aware that among those documents that you received from CDC, the August 11 documents, that there are findings from the CDC investigations in May, June, and July, those findings showing that at least two, and possibly three of the five clinics investigated by CDC, that it was established that there was a statistically significant positive relationship between an increased number of dialyzer reuses and an increased likelihood that patients at these clinics would contract an infection? Are you aware of that?

A. I don't believe so and I don't think there was a similar type of finding indicated in the MMWR.

Q. I didn't mention that.

A. That is the information I have from CDC. I am talking about——

Q. Obviously you didn't receive all of the information. I think we have established that quite clearly. You received about 11 inches of paper from CDC on August 11. What I am trying to tell you is this information was included in that parcel of documents which you received on August 11. That is why I asked you if you were aware. You said you weren't. Do you think this would have been germane, and perhaps even worthy of being considered for inclusion in the assessment report had you known about it?

A. Certainly.

Mr. RISEBERG. Are we pretty close to the end?

Mr. MICHIE. Yes; we are doing fine.

By Mr. MICHIE.

Q. The assessment report does make reference to the FDA survey in three States; California, Ohio, and Massachusetts, and the District of Columbia, and the report does refer to the D.C. survey finding. For example, "The incidence of infection," and I am using the term "infection" in a generic way, "appeared to be more frequent among the free standing facilities with a concentration in those cases which practice reuse of blood lines and dialyzers." However, NCHSR did not receive the other survey results in time to incorporate them into the assessment report. Isn't that correct?

A. We had received the D.C. report in sufficient time to incorporate it.

Q. I am talking about the others.

A. We did receive the draft of the Ohio report just about the week or week before we were providing the document—the assessment to Dr. Windom. I went through it quickly——

Q. Which one was that,

A. Ohio. So we did have that. We did not have the California, nor the Massachusetts report available to incorporate into the document.

Q. You didn't have California?

A. No.

Q. For example, let's talk about California for a moment. Would it not have been pertinent for the report to have cited some of the findings in the California survey? Have you read it?

A. No; I have not.

Q. You have not read it?

A. No.

Q. I am going to quote passages from that report. For example,

> Education requirements for the job of reuse technician when specified were minimal. For example, one facility's requirement was that the person be at least 16 years of age and be able to read and write English.
>
> Facilities are frequently not adhering to their protocals and the general lack of quality control and quality assurance procedures indicates that at least some of the reuse programs are not operating in a state of control.
>
> The median concentration used for disinfecting reused dialyzers appears to be in the two percent to three percent range. Many of the facilities were unable to indicate the concentration of formaldehyde used in the disinfection process.

And lastly,

> Among all the quality controlling procedures for reuse that were observed in the sites visited, the testing for the amounts of formaldehyde disinfectant residual was the worst.

Now, wouldn't these findings have been worthy of conclusion in the assessment report had you received that copy soon enough, or if Dr. Windom's office given you time enough in order to perform a thorough job on the assessment? Wouldn't these comments, these findings have been worthy of inclusion in the assessment report?

A. The findings of these surveys?

Q. Of the California survey that you say you have not read yet but I believe you did receive——

A. Or any of the other material that you have referred to, would add additional information pertaining to problems that have been identified. However, if one looks at our findings and conclusions and recommendations, I don't believe they would modify them to that extent, since we already believe that we need more information. We indicated that there was a lack of reporting or no reporting of infections. We indicate the need for more in information. We indicate the need for standards. We indicate the need for FDA to address the good manufacturing practices. Therefore, while this material does exist, and certainly should be reviewed and could add some insight, the conclusions and findings and recommendations that OHTA prepared to Dr. Marshall I think address these issues, and if they were followed, could correct them.

Q. Mr. Erlichman, how can you make that statement when you haven't even read the material that was sent to you, 11 inches of documents that was sent to you by CDC on the 11th of August as well as the California report which I am sure you know is a rather voluminous report and we have only read a few excerpts from it—how can you make that statement without reviewing that material?

A. I make that statement because your staff has looked at this, has presented its findings through the hearing, and problems that you think are associated with reuse. We have looked at a lot of the material. We have discussed this with numerous people, as you have indicated, and it seems that the areas we have addressed would improve the quality of the reprocessing and the other areas would provide additional data to better understand the advantages and disadvantages of reuse.

Q. Based upon your knowledge to date, as a health sciences anaylst, and having played a key role in the NCHSR assessment, do you believe it would be wise at this time to encourage increased reuse in dialysis clinics bearing in mind that about 40 percent of the clinics still choose not to reuse? Do you think it would be wise to encourage them to increase reuse? Would that be wise move, Mr. Erlichman?

[Pause.]

Q. Mr. Erlichman——

A. Just a minute. You ask a very interesting question.

Q. And I am looking for a yes or no answer.

A. I don't believe I could answer that yes or no.

Q. Why not? You have——

A. Because I said I agreed with Dr. Marshall's comment that was in a memo that accompanied our document to Dr. Windom that indicated that the current—while the current information does not provide evidence that multiple use is without hazard, neither does it demonstrate sufficient grounds to abandon reuse, which would make it difficult to recommend to somebody to increase the practice of reuse.

Q. Let me finish though. I asked you——

A. There are many factors involved.

Q. I asked you a question, in light of what you know now, in light of the fact that we know that the data base is inadequate, in light of the fact that we know that all reporting to FDA as well as to CDC about these infection outbreaks is entirely voluntary, in light of the fact that your own report states that there are not even specific questions within the CDC survey document asking about the increase in infection incidents—you recall that again——

A. Would you say that again?

Q. The fact that you state in your report on page 28—you state in the report that there are not even specific questions in that annual survey by CDC that ask about the increase infection incidence—isn't that correct?

A. Yes.

Q. The fact that we know that since March or April of this year that there have been at least eight outbreaks, only five of which CDC has investigated, simply because they don't have enforcement powers they only investigate when they are invited to visit the facility by both the State and the clinic. The fact that we know now that the AAMI guidelines, the AAMI recommended practice only attempt to address the reprocessing of dialyzers but not bloodlines and not transducer filters and not dialyzer caps, the fact that you know all of this now, Mr. Erlichman, let me put the question to you again: Do you think it would be wise to encourage an increase in reuse in these clinics, yes or no, please?

A. At this time, knowing what I know I think it would be more possible for a facility to reuse—reprocess dialyzers to reuse more safety than before. Since we know all these things now——

Q. You know what? You know the absence of information. That is what you know.

A. You said there is an inadequate data base. There is a data base. It is not based on clinical trials.

Q. It has not been tested. It has not been assessed. The CDC annual survey has not been assessed. Isn't that correct?

A. The outbreaks—that is what the CDC themselves have said.

Q. Don't you believe them?

A. Sure. I don't question something they say.

Q. That is in your report?

A. That is what they themselves have said.

Q. They themselves have stated in that memo I gave you of July 8 that they feel that the data is so inadequate that they would not promote, tolerate, or prohibit reuse which, to me, tell me if I am wrong, means that the data base indeed is very inadequate and, again, I will ask you——

Mr. RISEBERG. CDC?

Mr. MICHIE. CDC.

Mr. RISEBERG. They don't represent CDC.

Mr. MICHIE. Would you have quarrel with their opinions——

The WITNESS. The CDC has made a distinction.

Mr. MICHIE. Indeed it has.

By Mr. MICHIE.

Q. My question to you is, due to the paucity of data, due to the fact that there are not adequate guidelines in place now, and probably wouldn't be for some time to come because they don't even address all of the disposables that are reused, just because of those two things, do you think it is wise at this time for anyone to encourage an increase in reuse, yes or no?

A. There are too many factors involved in that to say yes or no.

Q. Why is that, Mr. Erlichman?

A. Why is that?

Q. Why are there too many factors there to deal with? You wrote the report. Virtually everything I said to you was in your report.

A. I certainly did.

Q. But the one thing you didn't include in your findings and conclusions as well as recommendations is whether or not CDC or FDA or PHS or anyone for that matter should be in the business now of encouraging increased reuse among the dialysis clinics. Surely you would be able to answer that question yes or no. In your personal opinion do you feel it should be encouraged in any way?

A. Under what circumstances?

Q. Under the present circumstances.

A. You indicated there was a great difference in the way it was practiced from facility to facility.

Q. But you and I don't know because all of the reporting is voluntary. In all probability as Dr. Villforth stated, we are probably seeing the tip of the iceberg——

A. Would you repeat that statement?

Q. We are probably seeing the tip of the iceberg.

A. In regard to what?

Q. As to what is happening out there as far as infection outbreaks.

A. That is a statement of Dr. Villforth?

Q. Yes, Mr. Villforth, right here in sworn testimony.

Mr. Riseberg. Let's wrap this up.

Mr. Michie. Let's get him to answer the question.

By Mr. Michie.

Q. This is a very simple question. It is one that deals with your specific findings and conclusions and your recommendations. You recommend further study. You recommend improving data. You recommend this, you recommend that. My only question to you is as of this day, before all of this is done, do you think anyone should encourage reuse in these clinics?

A. If additional studies were obtaining information, if the facility was using adequate standards similar to the California standards, similar possibly to the AAMI standards, if they had adequate surveillance and quality controlling——

Q. You are putting a lot of ifs in there.

A. Some of these questions cannot be answered yes or no. From the information I have looked at, I would not recommend to a facility that they had to stop reusing. Whether to tell the facilities to reuse, I would discuss with them the material I have reviewed, the studies that show no association. However, they are not clinical trials or more information should be gathered and they would also probably look at economics, since you have indicated economics is an issue.

Q. You did too, didn't you?

A. Then I said you are entering other factors into this. If it was your desire to save money—if a facility's desire was to be economical, they might decide to reuse. I couldn't say to them encourage reuse on a yes or no basis.

Q. I am not suggesting you suggest anything to the dialysis clinics. I am asking you as you sit here today and having made virtually every point I made in this convoluted question that has gone on now for 20 minutes—I am asking you a simple question: Because of the absence of data, because of absence of knowledge, because of the absence of adequate guidelines, standards or whatever you want to call them, at this time would you encourage an increase in reuse? In other words, would you want to go from 60-percent reuse in the clinics to 90 percent or 100 percent? How far would you be willing to go? That is the point. Should be encourage reuse or should be try to not encourage it simply because we don't have the information we need to determine if in fact it is safe and efficacious?

A. If we didn't want resue in the additional 20 percent, we don't want reuse in the other clinics. I think that the data base—a lot of people were satisfied that in the short term there didn't seem to be a problem with reuse. People might not reuse but felt that the information they were aware of—the concern was long term problems with the formaldehyde exposure, with the possible reduction in clearance. Those issues were never resolved. So that even when we have all of the facilities following standards for reuse, that would improve the quality of reprocessing drastically, we still would need to determine the long-term effects of the formaldehyde and the clearance. So if there is a factor, and I don't know the answer to that, when you say will you tell a facility to reuse, I would say I don't know the long-term effects of the formaldehyde, and the clearance. This is why we recommended additional studies and, therefore, it is not always possible to answer your question yes or no.

Q. Are you aware that HCFA has published a final regulation to reduce dailysis reimbursement rates beginning on October 1 of this year? Are you aware of that?

A. Yes.

Q. Does it not stand to reason, Mr. Erlichman, that for economic reasons these reductions probably will result in increased reuse?

A. I am not exactly sure that is the case. Facilities reuse to save money. But in the equation that they use to determine whether or not they are going to reuse is not necessarily total reimbursement but it might be the cost of the dialyzer, which has come down, so they would still need to determine the difference in the cost of the reprocessing, versus its single use, and along with our recommendations is the request for standards and it might not be—if that enters into the formula, it might become more expensive——

Q. If what enters into what formula?

A. If standards are required——

Q. Enforcement Federal standards?

A. That is correct, which includes quality control and certain qualifications of personnel, then if those costs are entered into the formula, facilities might not reuse even though the total reimbursement has been decreased.

Q. What has happened over the past several years, Mr. Erlichman?

A. There has been an increase in the number of facilities that reuse.

Q. Why is that?

A. Because they found it economical.

Q. In what respect?

A. But I don't know if the increase——

Q. In what respect was it economical? Is it because——

A. They found it less expensive.

Q. And therefore they could make more money, they would turn a better profit?

A. Or use it in programs in the hospital.

Q. Correct. So, again, I am going to ask you this question, one more time, and we will try to see if we can understand one another. Are you aware that HCFA has published a final regulation to reduce the rates—you are aware of that.

Does it not stand to reason that if you reduce the rates—if you pay these clinics less, does it not follow that in all probability there will be an increase in reuse in order to save money to make up the difference? Doesn't that make sense?

A. In the past that was correct. In the past new dialyzers would cost $25 to $30 so there was a much larger difference between the price of single use versus reuse cost to the facility.

Q. How long ago was that—at least 3 or 4 years?

A. Yes.

Q. A good while back.

A. Yes; but the increase in reuse in the last couple of years might not be anything like it was five——

Q. In the last 2 or 3 years?

A. The increase in reuse today might not be the same—the increment in the increase might be not the same when the dialyzer cost $25. Today they are somewhere in the vicinity of $13. The facility has to look at their savings. If the facility is already reusing, we have been made aware—if they were not reusing blood lines, to save money they might be using blood lines——

Q. How do you feel about that?

A. I feel it is a different question when it comes to whether a facility will start to reuse when they haven't. There is a lot of procedure, a lot of plumbing, so they have to take a lot into consideration.

Q. Does it not stand to reason that if you lower the compensation, the reimbursement, that it is going to encourage an increase in reuse?

A. It might.

Q. It might?

A. I said you would have to look at the formula that was used. A lot of of facilities, if they follow regulations——

Q. What regulations, Mr. Erlichman? There are no regulations, are there?

A. Excuse me?

Q. You said if they follow regulations. I said what regulations?

A. We are talking about down the road.

Q. Do you know the estimate that FDA has provided with regard to promulgation of GMP's for these devices, do you know the time estimates they have given?

A. I don't think so.

Q. Three to five years. Are you willing to wait that long for these regulations?

Once again. Let's go back to the question. You said, yes, it might increase reuse. We were talking about regulation. I pointed out to you that the FDA had told CBO that it will take anywhere from 3 to 5 years and my question to you was are you willing to wait that long, Mr. Erlichman, and do you think the patients should wait that long for these regulations which would hopefully provide some modicum of quality of care?

A. No; I do not.

Q. You would not want to wait that long?

A. If you don't understand my answer then I guess I didn't understand the question. You ask long questions that are difficult to answer. You don't know what part I am answering.

I would not like to wait 3 to 5 years. I believe we stated in the document that standards are needed—or regulations, if you will—needs to be some control over the way reprocessing is practiced in the facilities so that it is done adequately.

Q. In light of the fact that you don't want to wait that long, do you think it is wise during that period for anyone or anything to encourage increase in reuse?

A. If we relate the request of increase in reuse to the fact that I can at the same time feel that there are regulations in place to adequately address the reprocessing, I would feel more comfortable with facilities practicing reuse.

Q. And, therefore, am I to understand you correctly that you would not think it wise unless and until we have this quality control to encourage an increase in reuse?

A. I, personally, do not.

Q. You do not what?

A. Would not encourage reuse if we do not have quality control in place regulations or adequate standards that would assure facilities practicing reuse.

Q. In the interest of whom?

A. Patients.

Q. Why?

A. That is an obvious answer.

Q. Tell me. It is not obvious to me.

Mr. RISENBERG. Let's make that the last question.

By Mr. MICHIE.

Q. Why, why is it in the interest of the patients?

A. They are the ones receiving the treatment and they are the ones whose health care we are responsible for.

Q. Are these patients not very frail, anemic, sick people, who, if they do contract an infection, that it is a lot more serious than perhaps if you or I do?

A. With their high mortality rate, that possibly is the case.

Q. Isn't that the foundation for your concern?

A. Yes.

Q. Thank you.

This deposition is in recess until further notice. I want to inform you that you are subject to recall.

Thank you, gentlemen.

[Whereupon, at 5:30 p.m., the taking of the deposition was concluded.]

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

August 28, 1986

Mr. Richard J. Riseberg
Chief Counsel
U.S. Public Health Service
U.S. Department of Health and
  Human Services
Parklawn Building, Room 4A53
5600 Fishers Lane
Rockville, Md. 20857

Dear Mr. Riseberg:

I have reviewed transcripts of the appearance of your clients, Drs. John E. Marshall and Enrique D. Carter and Mr. Martin N. Erlichman, at depositions of the Special Committee on Aging on August 22 and August 26, 1986. I have noted your clients' refusals to take the oath that Committee Rule 6.3 provides for the court reporter/notary public to administer at the outset of a deposition.

Based on the remarks of your clients and yourself at these depositions, I understand your clients to have raised two objections. First, you have questioned the legitimacy of the Committee's issuance of subpoenas directing witnesses to be examined by Committee staff at deposition, without the presence of Members of the Committee. Second, you have questioned the authority for an oath to be administered at a Committee deposition by anyone who is not a Member of Congress.

I request that you communicate to your clients that, upon consideration of these two objections, as Chairman of the Committee, I have overruled both objections. First, section 104(c)(1) of Senate Resolution 4 explicitly authorizes the Committee to require the attendance of witnesses by subpoena and to take depositions. Your apparent contention that the deposition authority does not authorize depositions by Committee staff is incorrect. The word "deposition," in contrast to the word "hearing," refers to examination by staff only. This interpretation of the word "deposition" is the only interpretation that is consistent with well-established congressional practice as well as the common meaning of the word in extra-congressional legal contexts. I rule that the Senate has authorized the Committee to subpoena witnesses to testify at depositions conducted by Committee staff.

Second, Committee Rule 6.3, which provides for the administration of oaths at staff depositions by "an individual authorized by local law to administer oaths," is consistent

with governing legal authority. Your contention that section 104(c)(2) of Senate Resolution 4, which authorizes the Chairman or any Member of the Committee to administer oaths, precludes a notary public from administering an oath at deposition is incorrect. Section 2903(c) of title 5 of the U.S. Code, in concert with section 104(c)(1)(G) of Senate Resolution 4, pursuant to the Senate's constitutional rule-making power, authorizes administration of oaths to witnesses at Committee staff depositions by individuals authorized by local law to administer oaths. Accordingly, I rule that your clients are required to take an oath to be administered by any individual designated by the Committee staff who is authorized to administer oaths by local law.

I would appreciate your advising each of your clients who has refused to be examined by Committee staff at deposition under an oath to be administered by a notary public of my rulings on their objections. If Drs. Marshall and Carter and Mr. Erlichman remain unwilling to comply with the requirements of the subpoenas with which they have been served, subpoenas may be issued compelling their attendance at a hearing of the Committee in order for them to show cause why they should not be held in contempt of Congress. Please advise Mr. James F. Michie, Chief Investigator for the Special Committee on Aging, and Mr. Morgan Frankel of the Office of Senate Legal Counsel, of your clients' intentions.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

THURSDAY, SEPTEMBER 11, 1986

Washington, DC.

Deposition of John E. Marshall, Ph.D., called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 1:10 p.m., before Joyce Northwood, a notary public in and for the District of Columbia, when were present on behalf of the respective parties:

Appearances:

For the Special Committee on Aging:

James F. Michie, chief investigator.

David Schulke, investigator.

Christopher Jennings, professional staff member, U.S. Senate, Special Committee on Aging, room SDG-33, Dirksen Senate Office Building, Washington, DC 20510.

On behalf of the deponent:

Richard J. Riseberg, Esq., chief counsel, Public Health Service, room 4A53, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Mr. MICHIE. We'll go on the record now.

My name is James Michie. I'm chief investigator for the Special Committee on Aging of the U.S. Senate. This proceeding is now reconvened, the first session having been held on August 22, 1986.

Present with me here in room SDG-31 of the Dirksen Senate Office Building is committee investigator, David Schulke, committee staff member, Christopher Jennings, the notary public stenographer, Joyce Northwood, and deponent, Dr. John E. Marshall, Director of the Center for Technology Assessment, U.S. Public Health Service. Dr. Marshall is accompanied by Richard Riseberg.

On August 18, Dr. Marshall was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging for the purpose of being deposed by committee staff on August 27, 1986. Due to Dr. Marshall's vacation schedule, he had agreed to undergo deposition on the 22d day of August 1986, and forwarded a letter to Senator Heinz stating so. Dr. Marshall did appear here in the committee offices on that date but declined to be sworn for testimony on the advice of Mr. Riseberg.

Following his receipt of a letter dated August 28, 1986, and addressed to Mr. Riseberg from the chairman of this committee in which the chairman overruled Dr. Marshall's objections, Dr. Marshall agreed to return here. A copy of the chairman's letter of August 28, 1986, will be made a part of this deposition record.

Mr. RISEBERG. Before we begin, I'd like to make a brief statement.

The Department has asked me to indicate that it is volunteering to make Dr. Marshall available in order to cooperate with the Senate Special Committee on Aging in connection with its study of issues related to dialyzer reuse, and that Dr. Marshall is participating in today's interview solely on that basis.

He has been advised by attorneys for the Department that the subpoena served upon him is of doubtful legality and that the Department does not regard his participation to be compelled by the subpoena or governed by its terms. Nevertheless, subject to this understanding, he looks forward to answering any questions you may have.

An issue has arisen at some previous interviews as to the authority of the notary public to administer the oath to the witnesses. While the Department continues to believe that under the standing rules of the Senate only the Chair or a member of the committee has authority to swear in a witness, in order to cooperate with the committee and avoid further delay in getting to the committee's substantive concerns, Dr. Marshall has agreed to take the oath in question without conceding to it any legal significance it does not otherwise have. In so doing, Dr. Marshall has asked me to emphasize that whether or not sworn he would answer truthfully to the best of his knowledge.

Mr. MICHIE. Dr. Marshall, for the record, have you received a copy—if you will pass this to the deponent—have you read a copy of this letter dated August 28, 1986, from the chairman to Mr. Riseberg?

Dr. MARSHALL. No, I have not.

Mr. MICHIE. Would you like a moment to read it?

Dr. MARSHALL. Surely.

Mr. MICHIE. Please.

Dr. MARSHALL. OK.

Mr. MICHIE. Do you understand the chairman's rulings, which are basically that the subpoena that you were served with is indeed a valid subpoena, and that the oath you are about to take is indeed a valid oath? Do you understand those rulings?

Dr. MARSHALL. I have read the document.

Mr. MICHIE. Do you understand those rulings?

Dr. MARSHALL. No. I read the document, that's all.

Mr. MICHIE. Is that what you gather from the document as far as the rulings are concerned?

Dr. MARSHALL. I'm not able to interpret those. I don't have the necessary legal training or background to interpret those. I am prepared to take the oath and I'm prepared to take the oath freely.

Mr. MICHIE. I'm not asking you for interpretation, Dr. Marshall, I'm asking you do you understand from the letter to Mr. Riseberg that the chairman has ruled that the subpoena served on you was indeed a valid subpoena and his second ruling being that the oath you're about to take is indeed a valid oath?

Dr. MARSHALL. Well, let's deal with those one at a time. I understand he has said that he overrules the objection of counsel. But I also understand that I'm here voluntarily, as Mr. Riseberg has said.

What Mr. Heinz has said about the oath is not germane to me because the oath is something that I take, and I fully understand what taking an oath means. And as my counsel has represented to you, my answers will be the same whether I'm sworn or not, but I am willing to take the oath.

Mr. MICHIE. Prior to being sworn, Dr. Marshall, I want to remind you that if you knowingly provide false testimony under oath you may be subject to prosecution for perjury.

Are you ready to proceed?

Dr. MARSHALL. I'm prepared to proceed, yes.

Mr. MICHIE. Would the notary public please administer the oath to Dr. Marshall.

Whereupon, John E. Marshall, Ph.D., was called for examination, and having been first duly affirmed, was examined and testified as follows:

EXAMINATION BY THE CHIEF INVESTIGATOR FOR THE SPECIAL COMMITTEE ON AGING

By Mr. MICHIE.

Q. Would the witness please state for the record your full name, age, and home address.

A. I am John, middle initial E, Marshall, age 51. My home address is 2704 36th Street NW., Washington, DC 20007.

Q. With the exception of your having received appropriate and necessary advice and counsel, from the attorney, Mr. Riseberg, from the Public Health Service, regarding your rights as the witness in this deposition, has anyone prior to your appearance here today attempted in any way to influence your testimony in this deposition?

A. No.

Q. Have you prior to your appearance today discussed your testimony or that of anyone else—and what I mean by that are deponents who previously gave deposition here in these offices—have you discussed anyone's deposition testimony prior to coming here today?

A. No, no.

Q. Prior to your appearance here today you were requested to bring with you your appointment calendars and two black binder briefing books provided to you prior to this committee's March 6, 1986 hearing on reuse of disposable dialysis devices. Do you have these materials with you?

A. No.

Q. Why didn't you bring them?

A. Because I didn't see that they are germane to this. Those documents are documents that you have and we have discussed, in the context of my reference materials in case there were areas where I wanted to refresh my memory. And I didn't bring them because they are heavy and bulky and I didn't want to carry them.

Q. Are you an officer in the Public Health Service?

A. No—you mean a commissioned officer?

Q. Yes.

A. No. I'm a civil service employee.

Q. When did you become Director of the National Center for Health Services Research and Health Care Assessment?

A. February 1, 1983.

Q. Briefly if you will, what is your academic and training background?

A. I have an undergraduate degree, baccelaureate degree. I have a masters degree in experimental psychology. And I have a Ph.D. in experimental psychology, and I have completed an internship approved by the American Psychological Association in clinical psychology.

Q. In the interest of saving some time today I will refer to your Center as the NCHSR, the Office of Health Technology Assessment as the OHTA, that being a component of NCHSR, the Food and Drug Administration as FDA, FDA Center for Devices and Radiological Health as the Center, National Institutes of Health as NIH, Centers for Disease Control as CDC, the Public Health Service as PHS, the Health Care Financing Administration as HCFA, the Department of Health and Human Services as the Department, Arthur D. Little, Inc., as ADL, and the Association for the Advancement of Medical Instrumentation, as AAMI, A-A-M-I. Briefly what is the function and mission of the NCHSR?

A. We are responsible for supporting research aimed at better understanding of the organization, financing, and delivery of health services.

Q. And what is the function of the Office of Health Technology Assessment, OHTA, as a component of NCHSR?

A. OHTA carries out assessments of medical technology with respect to whether they are appropriate for reimbursement under the Medicare Program. And that means do they meet the standards of being of reasonable medical necessity. And its function in that particular role is to provide advice to the Health Care Financing Administration. That's its primary function.

It has an additional—other responsibilities assigned to it which may involve looking at medical technology issues for a variety of other organizations. Sometimes we do this for the Labor Department, sometimes for Defense Department, sometimes we provide information to the Congressional Office of Technology Assessment germane to what they do.

So there are special assignments. But the primary mission of that Office is to provide a Public Health Service assessment recommendation to the Health Care Financing Administration.

Q. Who is the Director of OHTA?

A. Dr. Enrique Carter.

Q. For how long a time has Dr. Carter served in that position and subordinate to you as the Director of NCHSR?

A. I believe he has been in that position since December 1983.

Q. What is the—specifically how many such assessments has the NCHSR performed for the Health Care Financing Administration?

A. Over what period of time?

Q. Since your coming there? Just roughly?

A. Yeah, probably 60.

Q. Has HCFA ever asked for health technology assessment concerning the reprocessing and reuse of disposable dialysis devices, to your knowledge?

A. They have not done so in my—during the time I was there. There may have been an earlier request because—no, that wasn't even to NCHSR. No, I don't believe they ever have.

Q. Did there come a time when NCHSR was requested to conduct an assessment?

A. Yes.

Q. When and from whom did you receive the request?

A. Dr. Macdonald, the Acting Assistant Secretary for Health. And that I believe was early in March 1986.

Q. What exactly to your recollection was it that prompted Dr. MacDonald's request for this assessment?

A. I think it was the impending hearing that was scheduled for the 6th of March.

Q. And whose hearing was that?

A. The Special Committee on Aging.

Q. Is that the only reason why the assessment was requested?

A. I believe so.

Q. Let met share with you a March 5, 1986, memo to you from Dr. Macdonald. Was this the first request for that assessment?

A. Yeah.

Q. You recognize the document?

A. Uh-huh.

Q. Prior to receiving this memo, did you not discuss conducting the assessment with Dr. Macdonald or someone on his staff?

A. Yes.

Q. And who might have been?

A. I believe I discussed it directly with Dr. Macdonald.

Q. And do you remember when?

A. It would have been roughly a week or so before that.

Q. Did he call you or did you call him?

A. I don't recall.

Q. Was it——

A. Probably I raised it with him.

Q. Was this in a meeting or in a telephone call?

A. It was in a telephone call.

Q. So, in other words——

A. And it was in the context of he was at that time my supervisor, and it was a recommendation that I made to him as my supervisor.

Q. Why did you——

A. It's something that I thought should be done.

Q. Why did you think so?

A. Generally we are looked on as a place that puts together information from a variety of sources, and at that point in getting ready for the hearing, it was clear to me that there were a number of people, number of agencies, that had been involved in this issue. And I felt that it was probably appropriate for us to make a recommendation in the testimony, in the opening statement, that we were willing to take this kind of a more serious look at the issue than could be carried out when you were in the short time between when the hearing was announced and the Department was requested to submit a witness and the time of the actual hearing.

And so I thought that it would be worth making sure that we had a document that showed that there had been a comprehensive review of the situation, some time early—as soon after the hearing as possible.

Q. This call that you made to Dr. Macdonald, was this after you learned that you were going to be the principal PHS witness at that hearing?

A. Oh, I'm sure of it. I mean I would not have had that kind of interest in it otherwise. NCHSR had not been previously involved in—you know, in these issues.

Q. During the discussion with Dr. Macdonald, did either of you touch upon HCFA's impending proposed regulation to reduce dialysis reimbursements?

A. No.

Q. This was not discussed at all?

A. This was not discussed at all.

Q. Getting back to the March 5 memo, "please complete a review and provide me with your conclusions with respect to the safety, efficacy, and cost effectiveness of dialyzer reuse within 60 days," at the time you received this request did you request whether such an assessment involving safety, efficacy, as well as cost effectiveness could be completed in only 60 days, this in light of the fact that it takes OHTA an average of 9 months or more to complete such a health technology assessment, did you question that?

A. No; in fact 60 days was my recommendation.

Q. What did you base that on?

A. I based that on what I had already seen on the record, I based in on what I had understood to be the level of complexity of the issue. This did not appear to me, given the exposure that I had to the literature to be, nearly as complicated as the issues that we normally look at when we do an assessment. And it seemed to me that this could be done much more quickly.

Q. So you felt at that time that this assessment could be done in less than a third of a time that an assessment on average takes your organization to do; is that right?

A. That's right. I felt it could be done in 60 days.

Q. Didn't Dr. Carter, Director of the OHTA, and Martin Erlichman, OHTA scientific analyst assigned to this assessment, express to you concerns about 60 days being unreasonable as far as timeframe was concerned for this assessment?

A. There was some discussion about that, but that occurred some time later when we made the decision to put a notice in the Federal Register. We—when we do an assessment, we put a notice in the Federal Register and then that requires the allowance of a certain amount of time for public comment.

When I first thought about doing this, it was not my intention to put a notice in the Federal Register. It was only afer the hearing when I saw the extent to which there were very strong feelings on the part of the witnesses on the other panels at the hearing that it occurred to me that we had probably better do—we had better put a notice in the Federal Register and be certain that there was an opportunity for all of these people to send in whatever information they had.

And so it was after that point in time when we had some discussion of whether or not we could have enough time to get a notice in the Federal Register and have the material completed.

Q. What was it though——

A. So that was a reaction not to the perceived scientific complexity of the issue so much as it was to the public interest and political interest and the need to afford enough time to make sure that there was an opportunity for outside parties at interest to collect information and provide it to us.

Q. But what was it, though, as early as March 5 that led you to believe that this wasn't a complicated issue? What was it that led you to that conclusion, Dr. Marshall?

A. Dr. Carter had identified some discussions based on his preliminary assessment of what the literature said.

Q. Did he advise you——

A. And he felt that he could——

Q. [Continuing.] That he could do it in 60 days?

A. [Continuing.] Do the assessment in 60 days.

Q. In other words, this was Dr. Carter's advice to you, not your suggestion to him; is that correct?

A. It was a mutual sort of discussion. You know, who it was said we could do it in this amount of time or that amount of time I don't honestly recall. Maybe he will recall that. But it was—there was a discussion and that time period fell out of the discussion. But it was not one with which he had any difficulty at that time and it was not one which I had any difficulty.

Q. So when you talked with Dr. Macdonald on the telephone, do I understand you to say that you and Dr. Carter had already had this discussion?

A. I think so. It's quite likely that it would have. I would not have made that kind of a phone call to Dr. Macdonald without having discussed it with the person who was going to do the work.

Q. Now, when did it happen, when did it happen that Dr. Carter and/or Mr. Erlichman came to you and were concerned about the 60 days? I think you mentioned it was some time—was it some time prior to the notice in the Federal Register or after?

A. No, it was after. It was not until—the next discussion that we had about it, as I recall, was in early June about the time that we received material from the committee.

Q. Not until then?

A. Right.

Q. But now I'm a little puzzled about something. When Dr.—when you and Dr. Carter agreed that 60 days would be sufficient—and of course this was back prior to your conversation with Dr.——

A. Dr. Macdonald.

Q. [Continuing.] Macdonald, isn't that correct?

A. Uh-huh.

Q. Did you ask Dr. Carter what he based his agreement on, what did he base his agreement on?

A. I don't know.

Q. So it was just a matter of you and he saying 60 days, and he said, yeah, that sounded fine, and that was it?

A. Uh-huh.

Q. There was no more discussion than that?

A. No. You have to understand that that's the nature of how he and I worked together, is that he is a man who does not require a great deal of detailed supervision, does not require a great deal of detailed checking up on. And he and I no matter what the issue agree on a timeframe for getting the job done. And I sent him off to do it. And I may casually say to him you're not going to be late, are you, you're going to be on time, aren't you? And he assures me he is. And he delivers when he says he's going to. And that's the nature of it.

Q. So you delegate a lot of authority to Dr.——

A. I delegate a great deal of responsibility in that regard, as I do for each of the four supervisors.

Q. Obviously you have a lot of trust in him or else you wouldn't; is that right?

A. Absolute, absolutely.

Q. Returning now to the March 5 memo, the first sentence in the third paragraph, "cost implications of the variance," and I'm going to paraphrase here. Cost implications of the variance in current practice for the use of dialysis supplies are of interest to HCFA and the Congress as well as the PHS.

What specifically was HCFA's interest in the cost implications at that early date?

A. I think you have paraphrased in a way that goes beyond what the memo says.

Q. Would you like to read the whole paragraph?

A. Yes.

Q. Please do aloud.

A. "Current practice for the use of dialysis supplies, especially the filter, varies among dialysis centers. While the FDA has approvd the filter as both safe and efficacious for one use, its reuse has never been formally assessed in the PHS. Further, the cost implications of the variance are of interest to the HCFA and Congress as well as PHS, and there is need to assess between single use and multiple use of dialysis filters."

Q. What was HCFA's interest in the cost implications at that early date?

A. I can't address that. This is not a memo that I prepared.

Q. Well, I understand that. But I mean you said you had a discussion prior to this memo being prepared.

A. Right.

Q. Didn't Dr. Macdonald say anything at all——

A. Well, I would assume—I mean if I were to have this kind of discussion—and this is a hypothetical example—I would point out that the price for a dialysis was that—the reimbursement level for a dialysis should be sensitive to the costs of the supplies used in carrying out that procedure.

Q. Why is that?

A. Well, because the price of anything ought to be rationally related to the resources that you use to produce it.

Q. But to whose interest? In whose interest?

A. To the Government's interest, to the taxpayers' interest. It's the taxpayers that are paying for these dialysis procedures. Now——

Q. Would you be concerned about——

A. At that point——

Q. Go ahead.

A. At that point when we had this discussion, when I had the discussion with Dr. Macdonald, I had an understanding that some of the issue that was of concern to people was an issue that had to do with potential fraud or at least some inequity in the payment system in that the reimbursement level was the same under a cost-based reimbursement system, which we were then some years away, is the same whether you used it or not, and there was some question whether people were billing HCFA for a new one each time but were reusing the old one.

So the concern at that point was around that issue because I had seen some inspector general material I recall that suggested that. So that was raised in that context.

I subsequently learned that all of the reimbursement was prospective, there was a fixed rate, it didn't matter whether you reused it or did not reuse it, you got that rate, and that was that. So the context of my discussion with Dr. Macdonald at that time would have been against that knowledge or against that perception that I had that there was an issue there of people charging for a new one whether they used a new one or not.

Q. Did I understand you to say earlier that at that time, as of March 5, that you were not aware of HCFA's proposed regulation or the preparation for HCFA's proposed regulation to reduce dialysis reimbursement rates?

A. That's correct, I was not aware of that.

Q. When did you——

A. My discussion with Dr. Macdonald did not involve any discussion of that.

Q. Approximately when did you come to learn about this proposed regulation?

A. Somewhere in late June or early July.

Q. Not prior to that?

A. No. I was not aware of the NPRM that was issued in April.

Q. I'm sorry, what was that?

A. Didn't HCFA have an NPRM in April. Wasn't the first notice of the rate change in April—didn't the first thing come out in April and the thing that came out in August was the final regulation? I was unaware of the NPRM.

Q. Could you give us the meaning of that acronym please?

A. Notice of proposed rulemaking.

Q. Thank you.

A. I believe that's correct. There had been a notice of intent to adjust the rate in April, but I was not aware of it.

Q. Do you have a definite recollection that you didn't know prior to then or is it that you don't recall having known prior to then?

A. I have a definite recollection that I didn't know before then. The reason I think that it was early July—the reason I'm certain that it was early July is it was something that came up really actually after my July 8 memorandum to Dr. Windom.

Q. After that?

A. Because it was that point that I heard some expressions of unhappiness from HCFA that did come at a bad time as they were getting ready to go ahead with the regulation.

Q. Did you at the outset of the assessment inform Dr. Carter or Mr. Erlichman or both that this was not to be a regular assessment and that it had to be done in a hurry?

A. Yes.

Q. Flesh that out a little for us if you would.

A. Well, it's what I've already said to you, that we planned to—in preparation for the hearing I determined that it would be good to do an assessment, for us to take a look at it. I think we were using the word assessment there as a term of art rather than a highly technical term that we normally use. So we agreed to do it in the 60-day period.

And the concern about how much time we would take only came about later when I decided to put a notice in the Federal Register. I had not anticipated putting a notice in the Federal Register when you I first raised it with Dr. Macdonald. As you see in this March 5th document there is no reference to an NPRM or actually—there wouldn't have been a reference to NPRM there. It would have been a Federal Register notice which would have been the same thing. Because these assessments are not rules.

Q. They're only advisory; is that correct?

A. Uh-huh.

Q. Did you inform either of these individuals, Dr. Carter or Erlichman, at any time during the course of the assessment that the assessment had to be completed in time to accommodate HCFA's schedule for publishing its final regulation to reduce the reimbursement rates for dialysis?

A. No.

Q. Specifically when and by whom were deadlines set for completing the assessment and for forwarding a report to the Assistant Secretary for Health?

A. That was a process that was driven by me. The original schedule for completion was to have been June 10. And on approximately June 7, the committee staff delivered to my office a large volume of material. And so I called Dr. Macdonald and told him that I thought that we need to take another 30 days because we needed to review that material.

And so we moved the completion date to July 10. Early in July I became aware of the—well, toward the end of June and early in July I became aware of the CDC MMWR report, and I became aware of the ongoing investigations that they were conducting with FDA. And I went to Dr. Windom and told him that we should not complete the report until we had some better knowledge of the outcome of those studies. And I asked him for another 30 days for the report to be complete on the 10th of August.

I determined that I would try to complete the report before the 10th of August because some controversy had arisen at about that time about the report, and it was clear that the committee staff was very interested in it, and I wanted to have an opportunity to have that in Dr. Windom's hands so that he would have an opportunity to review it with the agency heads before it became public.

So I made the determination that I would give him to him actually on the 4th. And I was 2 days later with it, which is a situation that I didn't like because I don't like to be late with things that I promised to my boss.

Q. Especially a new boss, right?

A. Especially a brand new boss, exactly.

Q. Now, as I recall, the Federal Register notice appears in the April 10 issue; is that your recollection?

A. It was early April, yeah. I'll accept that date.

Q. Pardon?

A. I'll accept that as the date.

Q. All right. When did you make the decision to publish this notice?

A. I didn't. I was not part of that—oh, you mean the notice that we were going to do an assessment?

Q. Yes.

A. I would say it was somewhere toward the middle of March.

Q. Middle of March?

A. I don't recall the date which our notice appeared in the Federal Register. It was early April.

Q. It was early April. But it would be good to get a copy of it.

A. If you have one.

Mr. MICHIE. Do you have one?

Mr. SCHULKE. Probably here in the Federal Register——

Mr. MICHIE. Let's take a 5-minute recess.

The WITNESS. Well, it was——

Mr. SCHULKE. I know it was April 10.

The WITNESS. Ours was the same—can we go off the record for a moment to clarify?

Mr. MICHIE. I will tell you what, while we retrieve the document let's go into a recess for a couple of minutes.

[Short recess.]

Mr. MICHIE. Back on the record please.

That's a letter to the chairman. Let the record show I've just handed the witness—just handed the witness a letter—what's the date of that letter?

Mr. RISEBERG. Federal Register notice?

Mr. MICHIE. Attachment to a letter dated April 29.

The WITNESS. April 29, 1986.

By Mr. MICHIE.

Q. Written to Senator Heinz?

A. Uh-huh.

Q. What's the date of it please?

A. April 10, 1986, appears in volume 50, No. 169.

Q. Now, when was it that you think you made the decision or the decision was made to publish in the Federal Register?

A. As I said earlier, it was somewhere around the middle of March. Because I see here that our notice was actually dated April 3. It appeared in the April 10 Federal Register. So it was probably somewhere around the middle of March, probably within within a week of the hearing.

Q. Now, getting back to this deadline, these deadlines for the report, on June 9 was there a draft that had been prepared, that you had prepared to forward to the office of the Assistant Secretary for Health for the assessment of the report?

A. No; there was not a draft which I was aware of, which I had seen.

Q. A draft that you had seen. What about a draft that somebody was working on?

A. That I don't know.

Q. Wasn't the first deadline June 10?

A. Yes.

Q. For forwarding a report?

A. And I would assume that there would have been a draft at that point or close to it.

Q. But you had——

A. It had not been given to me to review.

Q. Was there a draft on July 9 that was being prepared for forwarding to the office of the Assistant for Health on July 10?

A. I suspect there was a draft in some form. It was probably something less than a complete draft.

Q. Had you read it?

A. No.

Q. Did you at any time during the period from February 15, 1986, to the present draft and forward to John Villforth, Director of the FDA's Center for Devices and Radiological Health any memos or notes marked "confidential" or "for administrative use only" regarding the NCHSR assessment or regarding any aspect whatsoever to the issue of reprocessing and reuse of disposable dialysis devices?

A. Not to the best of my recollection.

Q. Did you have——

A. We did send him a—we did send him a memo but it was not marked "confidential" or anything, asking him for additional information that FDA might have had. But that was—I'm not even sure that I signed that. I think Dr. Carter probably signed that. But I might have signed it.

Q. Did you have any such communications marked "confidential" or "for administration use only" with FDA Commissioner Frank Young?

A. Yes; I did.

Q. Can you tell us on approximately what dates you did communicate with him?

A. Oh, it probably would have been somewhere around the 15th of July. It was certainly after July 8.

Q. And what did that communication involve?

A. It was a list of documents that we had had which had on it indicated when we had—which of those we had not received from the Food and Drug Administration prior to July 8.

Q. What about to James S. Benson, Deputy Director of——

A. No; I had no correspondence with Mr. Benson.

Q. Did Henry Desmaris?

A. I had no correspondence with Dr. Desmaris.

Q. Dr. William Roper?

A. None with William Roper.

Q. Dr. Rickard and the PHS administrative secretary, anything for administration use only?

A. I do not believe I did; no.

Q. Anne Desmond, PHS executive secretary?

A. No.

Q. Dr. Donald Macdonald, former Acting Assistant for Health?

A. No.

Q. Bruce Artim? I believe that's spelled A-r-t-i-m.

A. That's correct. I sent no written documents to him.

Q. What about Dr. Windom, who replaced Dr. Macdonald?

A. Yes. I sent a confidential memorandum—I shared a confidential memorandum with Dr. Windom on the 8th of July. But I did not leave a copy of it with him. I retrieved it at the end of the meeting. It was not sent to him. It was laid in front of him at a meeting.

Q. Was that particular memo marked or stamped confidential? Do you recall?

A. I don't recall whether it was or not.

Q. I have here for your reference a June 10, 1986, memo to Donald Newman, Under Secretary for the Department, from Dr. Macdonald who was then Acting Assistant Secretary of Health, subject of which is reuse of hemodialysis devices?

A. Uh-huh.

Q. At the bottom of page 2 I think you'll find it states that this memo prepared by you; is that correct?

A. That's correct.

Q. And item No. 5 on page 2 beginning with the second sentence, it states, quote:

> The assessment will be completed on June 10 and will be transmitted with recommendations to HCFA at that time. NCHSR HCTA has found no evidence contradictory to the position which we took in testimony.

Is that your reading of it?

A. That's what it says. And I wrote that. And that's what I intended to say at that time.

Q. As the author of this memo, what was the basis for that statement to the Under Secretary? What was your basis for that statement?

A. I had had a discussion with Dr. Carter.

Q. Is that what your statement was based on?

A. Surely.

Q. And what did that discussion include—consist of?

A. I—my guess would be that I showed him this draft that I had done and said do you have a problem with this, is it all right to say this? And he read it and said that's OK.

Q. Isn't it the case, Dr. Marshall, that you and your staff had indeed received new information contradictory to the position you had taken at this committee's March 6 hearing on dialysis device reuse?

A. We—let me separate that into several responses because you said several things there.

Q. Please.

A. It is true that we had received material from the committee. It is not true that the material that we had received from the committee had demonstrated the need to take a position contradictory to the testimony I had given on March 6.

Q. Now, going back——

A. You understand what I've said?

Q. I'm not sure I do. I'm not sure I do—in light of your July 8 memo I'm not sure I do at all.

A. We are now talking about June 10. I'm not talking about July 8.

Q. All right.

A. So we need to keep it in that context.

Q. True. Going back up to this quote though, you state in the first sentence:

> The assessment will be completed on June 10 and will be transmitted with recommendations to HCFA at that time.

Why would you do this?

A. I think that when I wrote that I had forgotten that this was a—not an assessment I was doing for HCFA, that this was an assessment I was doing for Dr. Macdonald.

Q. Did you know——

A. Normally what happens is we simply complete these assessments. And in fact they normally go over Dr. Carter's signature to HFCA.

Q. Isn't it also possible that at that time you knew of HCFA's interest with regard to their wanting to publish in the Federal Register a proposed regulation to reduce the reimbursement rates?

A. No; I don't think it is likely.

Q. As a matter of fact——

A. And the reason I think that that's not likely is that this came about because the Under Secretary had a meeting with some people from the dialysis community and HCFA had been asked to prepare a briefing memorandum for that. And PHS was also asked to prepare it. So it was in response to something for the Under Secretary as background for a meeting that he was having with the constituency group.

Q. But hadn't by June 10 it already published that proposed rate?

A. Yes.

Q. But you didn't know about it?

A. No.

Q. You had no knowledge whatsoever, no one ever mentioned anything at all to you about it?

A. No; at that point in time the people in HCFA that I was dealing with, it was around the issue of heart transplantation. So I had lots of conversations about heart transplantation, but I didn't have any about this. Because normally the people we relate to in HCFA are not the people who issue regulations, they're not the program people, they're normally the people in the reimbursement and coverage.

Q. Didn't Mr. Erlichman and people in your staff review documents on the reuse on April 17 right here? Are you aware of that that they came here?

A. I don't know what the date was. I knew that they came down here and looked at documents, yes.

Q. Are you also aware that they reviewed, this committee opened its investigation files on reuse and allowed them to look at all those documents?

A. I'm aware of that. You made the offer to me and I accepted it and sent them down here.

Q. Are you also aware that they also identified documents that they wished to have copies of and were in fact provided copies of? Are you aware of that?

A. Yes.

Q. Do you recall receiving from Senator Heinz on June 9, the day prior to the date of that June 10 memo, comments along with supporting documentation in response to the NCHSR's April 10 Federal Register notice?

A. Yes; Mr. Cunningham delivered them to my office.

Q. Documents which did indeed affect the position you had taken at the March 6 hearing; isn't that correct?

A. I received those documents. I did not personally review those documents. And I am——

Q. Why did you—go ahead, please.

A. And those documents were documents which caused us to address some additional specific requests to FDA and CDC and NIH.

Q. Why then did you refer to those documents in your July 8 memo to Dr. Windom and state that within that collection of documents, PHS documents, that you and your staff had never seen before but were indeed germane to the assessment, why did you state that?

A. Because that was factually correct. Because there were documents there that are germane to this issue that I had not previously seen.

Q. And that did in fact——

A. But I didn't say that they were documents that were critical to it. I said they were documents that were germane to it.

Q. And also affected the position that you took in testimony on March 6; isn't that correct?

A. I said that my testimony might have been different had I been aware of those. But I didn't say it would have been

Q. Let's check that memo. Do you have that?

A. Sure.

Q. Let's see what you did say, Dr. Marshall?

A. Yes.

Q. Did you get your copy of the hearing record by the way? I left you one when I was in your office a few weeks ago, you know the green book?

A. Yeah, yeah—I guess I did. I don't recall that I've seen that.

Mr. SCHULKE. It's on page 544.

The WITNESS. Oh, this, yeah.

By Mr. MICHIE.

Q. Now, let the record show that the deponent as well as his counsel have copies of the hearing record on the March 1986 hearing that was conducted by the Senate Aging Committee on March 6, 1986. We're turning to page 544 of that record, which contains the first page of Dr. Marshall's memo to Windom, dated July 8, 1986. Is that correct, Dr. Marshall?

A. That's correct.

Q. Do you find that there?

A. Yes.

Q. Now, if you would, turn to page 546. And we'll read the paragraph, second to the last paragraph:

> After the hearing Dr. Macdonald directed me to carry out an assessment of dialyzer reuse. In the course of carrying out that assessment, it has become evident that communications within the Public Health Service is less than adequate. We uncovered serious omissions and inaccuracies in the testimony which had been prepared based on facts made available last March.

I'll read that again.

> We uncovered serious omissions and inaccuracies in the testimony which had been prepared based on facts made available last March. Some of these only came to light the day before the comment period for the assessment expired when we received several hundreds pages of information from Senator Heinz. Included in that were internal PHS documents that had not previously been shared with us.

Now, does that not in fact indicate that some of the materials you received from Senator Heinz on June 9 alerted you to what you later identified as serious omissions and inaccuracies in the testimony, Dr. Marshall? Is that not the case?

A. I stand on what I said. I said that some of the information that we received from Senator Heinz, from the staff, was material that we had not previously seen. But I did not say that that was the critical issue, I did not say that that was the bulk of what—of the information that caused me to question whether I had had all of the facts. But I say some of the——

Q. And you used the term "serious," did you not? It's right here.

A. But I didn't say the serious omissions—I didn't specifically relate the serious omissions to materials that I received from the committee staff.

Q. Well, now wait a minute——

A. And let me pursue that.

Q. Please go ahead, please.

A. Because to me the serious omission is the fact that FDA had draft testimony—had draft reports from the three State contracts available to it prior to the hearing and they did not share that information with me prior to the hearing. That was not information that was brought to light in the documents provided by the committee staff on June 9.

Q. Let's go over two sentences.

A. And that's the major point.

Q. The first sentence we're going to go over,

> We uncovered serious omissions and inaccuracies in the testimony which had been prepared based on facts made available last March. Some of these——

A. Well, let's do this a sentence at a time. That's why I separate those into two sentences.

Q. The two sentences are related.

A. Mr. Michie, did you write this or did I?

Q. I want to ask you a question. May I ask you a question?

A. You certainly may.

Q. The next sentence you start by saying "some of these." What are you referring to there when you say "some of these"? Some of what?

A. Some of these facts.

Q. Some of these serious omissions?

A. No, some of the facts.

Q. Where do you see the word facts in here?

A. In the previous sentence.

Q. You're saying that that refers to facts made available last March?

A. Right, yes.

Q. So you're saying that some of these only came to light the day before the comment period for the assessment?

A. That's right.

Q. So what your testimony is is that right there you're not talking about the serious omissions and inaccuracies, you're talking the facts?

A. I'm talking that have only now—these facts were not available last March, these facts have only now been brought to my attention.

Q. Are you saying there's no connection between the facts and serious omissions?

A. No, not at all.

Q. So there is not a connection?

A. Certainly there's a connection. Some of the facts were serious, some were trivial.

Q. So therefore is it not true that some of the material that was provided to you by Senator Heinz did in fact reveal some of the serious omissions and inaccuracies?

A. Some of it influenced my judgment about what we should do next.

Q. The question again: Did the material, some of the material, two pieces of the material, given to you, whatever number you want to use, given to you by Senator Heinz on June 9 reveal to you some, a few, or whatever number you want to use, the serious omissions and inaccuracies that you talk about here?

A. No, I'm not willing to say that. Because I don't think that that's correct.

Q. What is correct?

A. I think the information I received from the committee or that we received from the committee caused us to go back and have additional discussions and to ask for specific documents. But the serious omission question is really a reference to a different issue. It's a reference to material from those contracts.

And we did not receive material from those contracts in what was submitted to us by the committee that we had not—we received material from the committee germane to those contracts but it was not stuff that we hadn't previously seen.

Q. Are you saying, Dr. Marshall, that in this June 10 memo or rather——

A. No. We're talking about the July memo.

Q. In the July memo that you were talking about the State contracts; is that what you're saying?

A. That was one of the main issues, yes, sir.

Q. One of the main issues?

A. Uh-huh.

Q. Did you on the day of your testimony before this committee intend to perform an objective, thorough, and complete assessment of reuse?

A. Absolutely. It's the only kind we do.

Q. Is it not the case, Dr. Marshall, that on March 6, as you testified before Senator Heinz, chairman of the Aging Committee, and informed him of the decision to conduct the assessment, that you knew it would not be an objective, thorough, and complete assessment; is that not the case?

A. That's not the case. I mean the case is that I offered to do an assessment, and I offered to do an assessment according to the standards and rigorous standards of objectivity that normally accompanies all of our assessments. And that's partly because the people who do them are competent, honest scientists with a great deal of scientific integrity, and it's partly because it's a public process and if you screw around with it you're going to get caught and reflect poorly on the Center and Government.

Q. Isn't it a fact—I'm sorry, were you not finished?

A. I'm finished.

Q. Isn't it true that your plan at that time was to go through the motions of an assessment in order to accommodate HCFA's plan to reduce reimbursement rates and to placate Senator Heinz?

A. That's categorically wrong. In the first place, I don't have the time and we don't have the staff to go through motions. If we were going to take on the assessments, we were going to do it right and we were going to do it right consistent with the level of effort. To be sure it was not a 9-month level of effort. It was a 60-day level of effort, but that was based on our judgment as to what we saw as the issues and available data that needed to be reviewed and that was very much different because we knew there was not going to be a lot of literature and information to look at.

Dr. Carter was fairly certain that he was not going to find something because when he—when we call up the computer search of what the literature says, that's pretty conclusive. I mean we—that stuff is well annotated. That's the first part.

The second part is that there had been no discussion with us at the time of the hearing, either prior to the hearing, in getting ready for the hearing, or after the hearing about HCFA's proposed regulations. So I didn't even know that HCFA was proposing regulations with respect to changing the rate for reimbursement. So that could not have been the case.

The third issue you raised did it have something to do with placating Senator Heinz, I didn't see the Senator in need of placating. I saw myself at a hearing.

Now, I certainly did feel that it would be appropriate for the Department to say to the Senator we are willing to do something less than the kind of full-fledged clinical trials that he seemed to be pressing for in the hearing. But as I made clear in my answers I believe at the hearing, I didn't think that a clinical trial was appropriate. And I maintain that position today.

So I don't agree to any of the contentions you made in that last question.

Q. Did you not inform Dr. Macdonald, the then Acting Assistant Secretary for Health on or about March 7 of this year, the day after the hearing, that the substantive part of your analysis had been completed and that there would be nothing new to be found regarding issue or reuse?

A. That was my view at that point in time.

Q. How did you inform him of this?

A. I probably sent him a note. But I may have called him on the phone.

Q. You think it might have been a note?

A. It probably was a note, uh-huh.

Q. Might that note be stamped "confidential"?

A. I wouldn't think so. I'm not one who stamps things confidential very often.

Q. Let me share with you now a note dated March 7, 1986, and stamped "confidential" from you to Dr. Macdonald?

A. OK.

Q. The subject of which is dialyzer reuse. Please take a moment to read your memo.

A. Yes. Right, OK, well, that's what I said. I thought those discussions occurred around the middle of March. I was off by a week.

Q. Again, I will ask you was it not your intention at that time to simply go through the motions of an assessment instead of conducting a thorough, complete, and valid assessment of this issue?

A. I would say again that that was not my—my intent was to do it as thoroughly as that. I clearly voiced my expectations here, that no matter what we found you guys would not like it unless it came out and said we need to do clinical trials. Because that was a reasonable inference from the Senator's questions and comments during the hearing I thought.

But, yes, at that time I thought that the substantive part of our analysis had been completed, that there would not be any literature that we would uncover that went beyond where we were. At that point in time I believed that I had all the evidence that there was from FDA and CDC with respect to what they knew.

I must remind you that we're talking about in March versus events that unfolded much later in June and July with respect to events in the field. But at that point in time there is nothing in that memo that should be construed as indicating that this was to be a sham or a charade or anything but an assessment. It was a frank appraisal to my boss that probably what we found would not be agreed with by the chairman or this committee's staff.

Mr. MICHIE. Let's at this time ask Mr. Schulke to read that entire memo into the record.

The WITNESS. Surely. He has a good reading voice.

Mr. SCHULKE. This is on the letterhead of the Department of Health and Human Services, typed in National Center for Health Services Research and Health Care Technology Assessment, dated March 7, 1986, stamped confidential. Note to Dr. Macdonald, subject dialyzer reuse.

> Prior to today's hearing with Senator Heinz on this subject I had assumed that we would carry out the assessment within the 60-day period that was specified in your March 5 memorandum. However, the original plan was to have used this as a way of deferring a response to the Senator. Unfortunately, it was decided that I should promise in the testimony to carry out this assessment. This means the process will be carried out under the careful scrutiny of committee staff, probably Mr. Michie.
>
> The substantive part of our analysis is completed. We had to do that for the testimony. There is nothing new that will be found. But because of the sensitivity of this and the aggravation of constituency groups as a result of these hearings, I think it best that we be allowed 90 days for carrying out the study. That will allow time for following our formal process, which includes a notice to the Federal Register and solicitation of comments from the cognizant specialty and subspecialty groups. In this case we will probably solicit comments from patient groups as well. They won't have facts to give us, but will give us strident opinions.
>
> I don't expect that Mr. Michie will perceive the study as anything but a whitewash, and consequently that will be the Senator's view. But I think we can forestall at least some criticism by going to 90 days. If you concur I will send you a formal request for extension without any of this background. Signed John E. Marshall, Ph.D., Director.

By Mr. MICHIE.

Q. Referring back to your memo that was just read, why did you feel it necessary to stamp it confidential Dr. Marshall?

A. I don't know. I mean that's—I doubt if I stamped it that. I suppose my secretaty did. But as I indicated before you showed this to me I'm not normally one who makes a lot of use of confidential stamps.

Q. Well, regardless——

A. Well, it certainly—you know, it would be appropriate to stamp it confidential. It was a sensitive document between myself and my superviser, not one that I wanted to have circulated widely to a lot of people. There are certainly as—you know, an opportunity for these—some of these statements to be misinterpreted. So I don't think it's inappropriate that it be stamped confidential, but——

Q. I wasn't suggesting that. I was just wondering why you had stamped it confidential.

A. Because in the process of things it got stamped confidential. I don't know why, I mean other than it was sensitive. And there is in the Public Health Service, as a lot of other places, documents are often circulated for comment. And this was not one that I wanted circulated for comment. This is one that I wanted——

Q. Wanted what?

A. You know, it was—a more appropriate designation would have been "eyes only."

Q. Eye only?

A. Yeah, something he needed to know but——

Q. No one else?

A. No need for Riseberg to know it or——

Q. No one else should know it?

A. It was a piece of information he needed to have.

Q. Looking at that first paragraph of your memo. Would you be specific and recount for us the original plan as you described it——

A. Yeah. Originally I said I thought we could do it in 60 days.

Q. Let me finish the question though. As a way of deferring a response to Senator Heinz. What was that plan, original plan, as a way of deferring a response to Senator Heinz?

A. My recollection is that we didn't—we had hoped that we could say, look, we're doing an assessment and therefore we don't have to make a commitment in this hearing on whether or not we're going to do clinical trials or not.

We'll say let's wait and see what the outcome of the assessment is. But let's not get into that hearing and get into a contest where he says do it, and we say we're not going to do it, and he says why aren't you going to do it, let's evade the issue right now, say we'll do an assessment and see where it goes from there. Because our position was—and we still think—that clinical trials were not appropriate. But we did not think that getting into that at the hearing was the way we could probably best accomplish it.

Q. Why not?

A. Because the hearing was a hearing that was attended by people who had very strong emotional feelings about it. It was covered by the press. And Government works better sometimes when the executive branch and legislative branch work things out.

Q. Are you referring to—when you say emotional people, are you referring to the patients, Dr. Marshall?

A. I'm referring to some of the other witnesses who were feeling very, very pressured by the situation, concern for their health and their life and potential adverse effects from the treatment they were receiving.

Q. Do you think they had cause to be concerned, Dr. Marshall?

A. I think any individual who is suffering from an illness that requires chronic hemodialysis has reason to be concerned.

Q. Why is that? Describe a typical patient for me, the classical dialysis patient, physically I mean.

A. There is not a classic dialysis patient. But——

Q. For example—go ahead.

A. There are people who have kidney function that is so compromised that absent access to dialysis they are not going to live very long. They are gone——

Q. Are they anemic?

A. No; they're toxemic.

Q. Can they also be anemic?

A. Can be. It depends on whether we're talking about primary or secondary renal disease. As we've already established I'm not a nephrologist or——

Q. You seem to know about it——

A. I probably know more than the average person on the street.

Q. Would you say a goodly number of these patients are frail?

A. I have no basis for making that judgment or not making it.

Q. Would you say that these patients perhaps in a general way, as a rule, if they contract an infection, that it's more serious than the average person, the consequences?

A. I would say that. But I would also say these were patients who were—who had come to a hearing, it was a hearing at which they were going to have an opportunity to say—to talk about a lot of things before a Member of the U.S. Senate that were problems for them, that they were worried about.

My surmise would be while I don't base it on any discussions that I had with any of those witnesses, based on experience with witnesses in that situation, they—you know, they are generally ready to see the executive branch take a shellacking. And they are easily excited about it. And they are very tender in their sense of what's going to happen. They want to see justice done from their perspective.

Q. Getting back though to this original plan that you mentioned in your memo as a way of deferring a response to Senator Heinz, who else participated in this plan? With whom did you discuss this plan, this original plan? Can you tell us? Did you discuss it with Dr. Macdonald?

A. I did not discuss it with Dr. Macdonald. It was discussed at a meeting where people from the legislative office were present and we were preparing testimony.

Q. To the best of your recollection, tell us who was at that meeting?

A. Well, obviously I was there. And I would think that Florence Hassle was there. Beth Geblehaus from HCFA was there.

Q. I'm sorry, that last name?

A. Geblehaus.

Q. Do you know the spelling?

A. Why don't I think of someone with a shorter—no, I don't. G-E-B-L-E-H-A-U-S, I believe.

Q. Anyone else?

A. No—there may have been other HCFA staff and other PHS staff. There were people there from PHS, from FDA, but I don't remember who they were. It was not Villforth and it was not Benson.

Q. Mr. Eccleston by chance?

A. It might have been Eccleston; Mr. Eccleston may well have been there.

Q. Mr. Kobren?

A. I don't remember whether he was there or not.

Q. Mr. Villarroel?

A. He may have been there. I don't remember more certain. I believe there—there were two women there from NIH whose names I don't know.

Q. Dr. Cummings?

A. Cummings and Striker were not there. They were people from the legislative office.

Q. Dr. Hirshalman?

A. No.

Q. Was Mr. Rickard there?

A. Rickard was not there.

Q. Was Ms. Desmond there?

A. No.

Q. Anyone from CDC?

A. Yeah; there was someone from the CDC office.

Q. Ms. Depister?

A. It was, yeah, Francie Depister was probably there.

Q. Anyone else from CDC?

A. Not that I can recall.

Q. Was this a strategy meeting of sorts?

A. Well, I would characterize it as a preparation meeting, it was——

Q. For the hearing?

A. Yeah. It was to review the draft testimony; it was to review Q and A's that had been prepared; it was to suggest—to make sure that we anticipate questions that would be asked by the committee staff and to make sure that we had all the factual information assembled that we thought we might need.

It was witness preparation, what I would characterize it, which means that Bart Flemming would have been there also—well, not necessarily. It seems to me that his staff may have briefed him separately after that and he was not at that meeting. Because he was at that time filling two or three other jobs. He was the other witness.

Q. What about Mr. Villforth, he was your backup witness, was he there from FDA?

A. Oh, he must have been, yes. I didn't recall that—I mean I can't recall the specific meeting. I'm responding in terms of people who typically would have been at a meeting like that.

Q. And approximately——

A. I don't even remember the date. It probably was the——

Q. A few days prior to the hearing?

A. A few days prior to the hearing perhaps, 2 or 3 days.

Q. Getting back to your memorandum and the first paragraph, this is a memorandum with the date March 7 stamped on it?

A. Uh-huh.

Q. Why did you find it unfortunate to have promised in your testimony to conduct the assessment? Can you explain that.

A. Yeah. Because I would rather not have had to do it.

Q. Why not?

A. Because we're busy, we don't have—we're short staffed, A; and B, I knew that it was going to be controversial and consume effort and energy way out of the proportion from what at that point I saw the issue to be.

Q. So, in other words, at that point you really didn't care to perform this assessment; did you?

A. It was not—I mean I offered to do it and, I offered to do it in good faith, but I—it was taking on work for which we weren't going to get any additional resources.

Q. And did you think at that time it was worth the candle so to speak, worth the effort?

A. Oh, I thought it was worth the effort to do it right if we were going to do it.

Q. Or if you were going to do it at all?

A. Yeah. I mean if we were going to do it, it was going to require a certain level of effort. But I would have been equally happy had the Senator said no there's no need to do an assessment. I mean I would have been maybe perfectly comfortable. We'd have kept Dr. Handleman and Mr. Erlichman working on their other assignments.

Q. Why would you be concerned about, quote, "careful scrutiny" of the assessment process by this committee's staff, why would you be concerned about that?

A. Because, Mr. Michie, I thought that meant that you would want to give us a lot of help, and you would be possibly give us so much help that it would obstruct our getting it finished on time. That's why I was concerned about that. I wasn't concerned that you would find some, you know, scientific oversight or some lapse of probity on the part of our staff. It was that you would help us with it and you would want to see various drafts of it and you would want to help us correct those.

That was my impression of how I had seen you wanting to be helpful as we got ready for the hearing. And that was what I meant by that.

Q. Could it also possibly have been that you were concerned that perhaps that careful scrutiny, looking over your shoulder so to speak, would perhaps interfere with some plan of yours?

A. No. I simply thought that it would interfere with the timely conduct of the activity. I thought that you'd be calling Marty Erlichman or Harry Handleman on the phone and saying how are you doing, did you know that CDC has found that or FDA has found that, well, what do you make of that? Well, here's what I make it of it. Well, is that what you really should make of it. And that would be really disruptive to the way we normally do these things.

And that's a chronic problem with this process I might add. Because we frequently get—as we perform other kinds of assessments, we frequently get the manufacturers who want to help us to do the assessment and they particularly want their attorneys to help us do the assessment. And there are a lot of people who think that these assessments are based on who has the best legal brief.

Doing an assessment is not an adversarial process. Doing an assessment is a scientific activity and that's done best in the way which scientists work, discussing findings, interpretations of those findings. I didn't want to be politicized, not in the partisan sense, but in the sense of being made that kind of a process which is how Congress proceeds or how the administrative, executive branch of the Government, proceeds, which is by discussion, negotiation.

I wanted this to be a scientific effort. And those are best done by scientists according to scientific rules.

Q. So do I take that to mean that you wanted to be left alone; is that correct? You didn't want us coming over there; did you? You didn't want us sharing our documents with you; did you?

A. No, I didn't say that.

Q. Oh, was that part of it OK?

A. I said I'm perfectly willing to take any information you had. I was delighted when Mr. Cunningham showed up with that pile of documents even though it was a little glich in the track because I had anticipated getting that over with in the next couple of days and get on to other work. But that has to do with my sense of process. That shouldn't be construed that I didn't want any information that the committee might provide to us. It was simply that I didn't want help that would protract the process.

Q. How could you possibly have completed the substantive part, as you put it, of the assessment as early of March 6 or 7——

A. Because Dr. Carter——

Q. [Continuing.] When you had not even published the Federal Register notice seeking any and all information from the public and the Federal agencies as well regarding the safety and efficacy of reprocessing and reuse? How could you possibly in light of that have told Dr. Macdonald that you had completed the sustantive part?

A. Times when we do assessments, there are hundreds and hundreds of journal articles to be read and digested and integrated into a whole. In this case we had already done a literature search, we had already reviewed that material for the hearing, we already had what we thought when I wrote this memo on March 7 was all of the information that the PHS agencies had.

Any my assumption was what we had in hand was the scientific data, and that the only other thing we would be receiving would be the comments from the constituency groups, from the public interest groups, and possibly from the committee. And I didn't anticipate that that would be as large a volume of information as it turned out to be.

But I think you would find if you went back and you—and perhaps you did—asked Mr. Erlichman how many journal articles he had found in June or in May that had been published prior to last March. I think the number would be very small, probably approaching zero.

Q. But again, I'm going to ask you——

A. But when I wrote that though, I honestly believed that we had all the information and that we would have some delay. Because it takes time to get public comments in and they are often times hard to integrate together. When you get responses from specialty and subspecialty groups, it's not unknown for us to get a response and 2 weeks later you get a second response that says, well, we've talked to more people and we think our position is 180 degrees from what it was 2 weeks ago, please disregard the first letter, here's the second letter.

But I felt that substantive part, scientific part, clinical part, I felt we had that data at that time.

Q. Who was it that led you to believe that?

A. Dr. Carter.

Q. All right. Now, let me ask you this though: When you were preparing for the hearing, isn't it a fact that you relied very heavily on the FDA and HCFA in the preparation of your testimony; isn't that——

A. Not HCFA.

Q. FDA? Isn't that the case?

A. I relied heavily on FDA and CDC and NIH. But I also relied heavily on what Dr. Carter told me independently.

Q. Well, would it be fair to say, would it be accurate to say, that you relied just as heavily upon FDA—when I say "you," I mean Dr. Carter as well—as you did on any other entity in the preparation of your testimony?

A. Oh, I think we spent more time with FDA and got more documents from FDA than from anybody else, surely.

Q. So at that time you were convinced, do I understand you correctly, that you had the substantive part, but at the same time you're telling Dr. Macdonald that you're going to publish a Federal notice?

A. Uh-huh.

Q. Why go to the trouble of publishing a Federal notice if you had thought you had it?

A. Because the notice in the Federal Register doesn't generate scientific information, it generates points of view, information on points on view of people who may be clinicians, may be scientists but also have a more broad perspective on it.

This is not an issue that is driven strictly be science and technology, this is an issue that's a broad public policy issue. It's an issue that, as I've already described, is one that is part of the value system and concerns of people on dialysis. It's part of that arena of things about which they are worried and have concern.

And we wanted to make certain that there was an opportunity for those points of view to be articulated and to be heard and for us to pay attention to them where that was appropriate and to make sure that we had that—that our assessment reflected that.

I have often questioned in my own mind and Dr. Carter and I have discussed on many occasions the utility of our publishing a Federal Register notice on any assessment. It—the tradeoff for utility of the information that comes to us from that versus the amount of time delay that it injects into the process is one that is very, very close to the margin.

But we do it because we believe that it's worth that investment in time to make certain that the assessment includes in it any statements from—other than from our scientists is about this issue and they are acknowledged and they are addressed just as in the preamble to a set of regulations you address all of the questions and comments that were sent to you. You may not accept them all, but you address them all.

And that's why we agreed to do this, because this was something that was a political and social issue as well as a technological issue. And we felt to have a balanced assessment, we had to do all of those.

Q. And so—but you keep referring back to scientific journals, articles, papers, and so on. At that time did it ever cross your mind that there may be some data or some information reposited in the files of the FDA or CDC, and did you ask them for any and all of their information?

A. The answer to the first question is that I assumed that they have some information in their files, but that I assumed that they had given us all that they had and that we had whatever information they in their clinical and scientific judgment deemed to be pertinent to it, yes.

Q. But, as it turned out later, what did you come to learn later?

A. What I came to learn later was that their view of what was pertinent was somewhat at variance with our view of what was pertinent.

Q. Somewhat?

A. Uh-huh.

Q. Just somewhat?

A. Just somewhat.

Q. So on April 10 you published the notice in the Federal Register, thinking at that time that, well, it's something we have to do, we might get a few comments, but in your opinion at that time the substantive part of the assessment had already been accomplished?

A. It was something I did that said that this is something we should do, it was something that we did because we wanted to afford an opportunity for comment and for information from those sources.

I did not anticipate that those sources would provide additional clinical or scientific data because I was fairly certain that if I had it it would be part of the hearing record. But I did not anticipate that that process would uncover anything that would cause us to make recommendations that were different from the position I had taken during the hearing, that's correct.

Q. Again, Dr. Marshall, I'd like to ask you: wasn't it your plan as well as the plan of the Office of the Assistant Secretary for Health, to go through the motions of an assessment in order to accommodate HCFA's regulation to reduce the dialysis reimbursement rates and at the same time to placate Senator Heinz?

A. And again I will say to you that there was no thought of that on my part, there was no discussion of that on my part. And there was—there certainly was an intent to avoid antagonizing the Senator, but I certainly didn't make the judgment that he needed to be placated.

Q. Did you not from time to time during the assessment inform Dr. William Roper, HCFA administrator, or Dr. Henry Desmaris, Deputy to Dr. Roper, or both, on the progress of the assessment?

A. I had no discussion about the assessment with Dr. Roper. I had one discussion with Dr. Desmaris, and that was some time after July 8. And Dr. Desmaris called me and he asked me whether we were going to be making recommendations to HCFA as part of our report, or assessment, when it was completed. And—well, he asked me first when I expected to have it finished, and second would there be any recommendations addressed to HCFA?

And I told him that I expected to have it finished by August 10 or before August 10 and that there would be no recommendations to HCFA in it, that it would all be recommendations dealing with things that I thought the PHS agencies should do.

Q. What about with Mr. Rickard, did you have any discussions with him about it?

A. I don't believe that I did, no.

Q. Did you during the course of the assessment discuss with either of the HCFA officials that I just named, Dr. Roper or Dr. Desmaris, the potential impact of the assessment findings and HCFA's plan to reduce the dialysis reimbursement rates?

A. No; I did not.

Q. Not on any occasion?

A. There was an occasion in a larger meeting where it was a meeting that was called to discuss my—what the Department's response should be to the Senator's letter asking for a copy of the July 8 memorandum. And at that meeting Dr. Desmaris allowed as how the timing of my memorandum was not real helpful to them.

Mr. RISEBERG. When was that?

Mr. MICHIE. When was that?

Mr. RISEBERG. After July 8?

The WITNESS. That was after July 8, yeah. When was the Senator's letter requesting a copy of that? It was July 14 or 16?

By Mr. MICHIE.

Q. I think it was either the 14th or the—I think it was the 14th.

A. I think it was the 14th, so it would have been after that meeting.

Q. That what happened?

A. Pardon?

Q. That what happened? What did happen?

A. There was a meeting that said, look, you know, there's this memo that you wrote and now Senator Heinz wants a copy of it, and how do we—what's the process by which we do this? Should the response be signed by the Secretary or by the Assistant Secretary for Legislation or by the PHS or—you know, and how do we go about sending this up to the Hill? What's the mechanism by which we do that?

And somewhere in the course of that meeting, Dr. Demaris did comment, gee, the timing of this could have been better. You know, we had this regulation pending and that was the only comment that was ever made.

Q. This had to do with HCFA's pending regulations?

A. Yeah, yeah.

Q. And was that the first time?

A. That was I think the first time that I was aware of that. Because I recall that I said, you know, what's that, Henry? And he told me. And I said, oh well, I'm sorry.

Q. Was he very disappointed about it?

A. No; I don't think so. Dr. Desmaris is a very pragmatic sort of chap, and he's not given to great emotional outbursts about things. It was an observation he made and passed on.

Q. Let me share with you now a July 10, 1986, note to Mr. Rickard—am I pronouncing that correctly?

A. Rickard, uh-huh.

Q. From Anne Desmond, the subject of which is hemodialysis.

A. Uh-huh.

Q. Anne Desmond is in the PHS executive secretary; is that correct?

A. I believe so.

Q. Do you recall having received a copy of this?

A. Yes.

Q. Item No. 1 in this note states:

> Ask John Marshall if he has kept Bill Roper or Henry Desmaris informed of the progress of his study. HCFA is proceeding with a new end-stage renal disease program that will reduce reimbursement rates for kidney dialysis. Obviously if that happens dialysis centers will want to shift to even more dialysis filter reuse since it's cheaper. Therefore if John Marshall reaches conclusions that reuse is a health hazard, it could put the HCFA folks in a quandry.

Now, did you follow up on this note, Dr. Marshall, and did you keep HCFA informed on whether or not you'd conclude that reuse is a health hazard?

A. No.

Q. You did not? Why not?

A. Because I didn't see that as a germane issue. I saw telling HCFA when I was going to finish the report that it would be issued on time, and that there would be no variance from the schedule. But, you know, that was—what HCFA's need was and what it was not was not what was at issue for us. We were doing an assessment for the Public Health Service. I was doing something that I was going to send to my boss, which he would presumably transmit to Senator Heinz. It was not something we were preparing to give to him.

Q. But surely you knew at that time that your assessment was going to impact on their regulation; did you?

A. I said on or about the 14th I knew that. I don't know when I first perceived this. This was not a memo to me, this was a memo to Rickard, which he gave to me some time I presume in the following week.

Q. I understand. But is it——

A. I certainly knew after that time it was going to impact on HCFA.

Q. That's why I'm asking you, since you knew it was going to impact on HCFA, and since you received this note, a copy of this note, and you knew of HCFA's interest, so that it wouldn't find itself in a quandary, did you at any time discuss with anyone at HCFA or through someone at PHS the progress of the assessment?

A. No. Other than to say that it would be finished when it would be finished.

Q. Was an arrangement made perhaps for you to give over information regarding the assessment to someone, to an intermediary who would then convey that information to HCFA?

A. No.

Q. There was no such arrangement?

A. There was no such arrangement. There was—you know, there was a—there was—well, not only was there no such arrangement with HCFA, there was not—I didn't discuss that and I didn't discuss this memo with Carter or Elrichman.

Q. You didn't discuss it with anyone?

A. No.

Q. Why not?

A. Huh?

Q. Why not?

A. Because I thought those processes were separate, and I wanted to maintain them as separate. Now, I am——

Q. Separate in what sense?

A. I want to be very clear about this.

Q. Please do.

A. I want to be very clear about this. Normally what we do in assessment, if there's any kind of potential for controversy about it, I do spend time talking to people about it, Dr. Carter does, his staff does. This was a situation where we didn't see this as an important thing to discuss with HCFA because we didn't know about the regulation. And once we—once I knew that there was a regulation, I was very, very careful not to discuss it with Henry or people on his staff.

And I had—I had opportunity to do that because I had several meetings with Dr. Roper and Dr. Desmaris during this time. Because as I pointed out earlier, we were getting ready for the announcement and decisions on heart transplantation.

But they knew—they knew we were doing this assessment and they weren't asking me about it and I wasn't telling them about it. I mean they weren't worried about the outcome. And I don't think that they were thinking that it was or would be a problem.

Q. Well, why would that memo be written by Ms. Desmond? She surely indicated in that memo you have before you that there was concern at a HCFA, the excerpt I just read to you?

A. I believe that this is a memo that does not refer—in fact, I don't believe it. I'm going to draw to your attention, this is not a discussion that Ann Desmond was having with Anna Boyd—I mean with HCFA. It's a discussion that she was having with Anna Boyd who works in the executive secretariat in the Secretary's office.

Q. That's correct.

A. Anna Boyd was the person who was staffing—do you want me to stop?

Q. Please, go on.

A. Anna Boyd was the person staffing the Under Secretary, who we mentioned earlier was having meetings with some patient constituency groups. And she was responsible for keeping the Under Secretary informed about this.

Q. Yes.

A. They had expressed interest earlier—she had been told earlier that the assessment would be finished on July 10. Now, people in the executive secretariat earn their living by tracking what we living bureaucrats are doing and by making sure that things appear when they are supposed to appear. So as a routine inquiry, she was informed when we delayed this from June 10 to July 10 that we were going to be a month later and that it was not going to be delivered on June 10 as we had said earlier.

You recall we spent some minutes earlier discussing Dr. Macdonald's memorandum to the Under Secretary in which he said that Dr. Marshall will have this by June 10. So this was a discussion between two very low level staff people in the executive secretariat. It was not a discussion with HCFA——

Q. I don't understand. How are you able to sit there and speak for Anna Boyd?

A. I'm not speaking for Anna Boyd. I'm telling you what it says in the memo.

Q. Yes. And what it says——

A. And I'm telling you what Anna Boyd's responsibilities were, and I was not speaking for Anna Boyd.

Q. It says in the memo excerpt that I read to you—I'm going to read it again—"Ask John Marshall if he kept Bill Roper or Henry Desmaris informed of the process of his study."

A. And the line above that says: "Anna also asks that we do two other things."

Q. Correct.

A. I'm not speaking for Anna Boyd. I'm reading what Anna Boyd is reported to have said by Anne Desmond.

Q. I'm going to continue to read it.

> HCFA is proceeding with a new end stage renal disease program reg that will reduce reimbursement rates for kidney dialysis.

Is that inaccurate to that point? Is there any inaccuracy there so far, what I've read, is there anything inaccurate?

A. I don't know what you mean is it inaccurate.

Q. I'm trying to see if—whether or not you disagree with what's stated there, that's all, the accuracy?

A. Do I disagree with the accuracy of that statement?

Q. Yes?

A. That HCFA is proceeding with a new end stage renal disease program reg. I didn't know it at that time but I know it now.

Q. And that it would reduce reimbursement rates for kidney dialysis? Wasn't that the purpose of the reg?

A. That's what it says here. I don't know that's what she's saying. I have never read that regulation.

Q. Do you want to challenge that?

A. No.

Q. I'll continue here:

> Obviously if that happens, dialysis centers will want to shift to even more dialysis filter reuse since it's cheaper.

Is there anything there that you disagree with?

A. Yes. I would like to know on what basis Ms. Boyd arrived at that conclusion. I would not necessarily arrive at the conclusion. I would disagree with that statement.

Q. What conclusion would you arrive at, Dr. Marshall?

A. I would arrive at the conclusion that dialysis centers who are reusing would continue to reuse and dialysis centers that were not reusing would probably for the most part continue to not reuse. Because those dialysis centers for other reasons, either because they didn't have the reprocessing equipment or because they weren't sure that they knew how to reprocess properly, or because the director of that center did not believe as a matter of clinical judgment that reuse was appropriate, I would not predict that there would be very much of a change in the rate of centers that reused or did not reuse.

Q. Are you saying, Dr. Marshall, that a reduction in the rates of reimbursement isn't going to encourage an increase in reuse? You're not saying that; are you?

A. I'm not saying that it would, I'm not saying that it wouldn't.

Q. What is it likely to do?

A. I'm saying I don't have any evidence either way—I think what it's likely to do is cause dialysis centers to look at additional ways of cutting costs.

Q. Including?

A. There are a whole range of things that I could speculate that they could do.

Q. Isn't reuse one of them?

A. They could decide to reduce the salaries or the profit that they were making in the case of a profit-making dialysis center. If it was a dialysis center in a hospital, they could shift some of the costs to some other kind of an account. They could start looking about for less expensive paper supplies, they could try to find ways of reducing their utility bills, they could——

Q. What are they going to do, burn candles? What would you suggest, kerosene lamps or candles?

A. I recall at one point when we went through the Federal buildings and removed half of the florescent tubes because——

Q. What about reuse?

A. There are a lot of things. Cut down on fringe benefits for employees and—if you will be patient—they may decide that they are going to decide to try to save money on that score as well. And they may decide to do that finding an alternate supplier for equipment they use.

They may decide to start reusing the whole apparatus rather than just the filter. They may cut corners on how they reprocess. You know, there are just lots of things they can do.

Q. So isn't——

A. But I want to be very clear that I would not have made the judgment that Anna Boyd there made in this statement, I would not say that it would—more dialysis—I would not say obviously if that happens dialysis centers will want to shift to even more filter reuse. I don't think she has any factual basis for making that statement.

Q. Perhaps she got it from someone at HCFA. Isn't that possible, Dr. Marshall?

A. It is certainly possible. But I don't say that it's probable. I don't know.

Q. That's correct.

A. And you don't know.

Q. Well——

A. So we should probably neither of us put words in Anna Boyd's mouth.

Q. At this point I think it's best for you to speak for yourself.

A. That's all I'm speaking for. And I'm working hard to keep you from speaking for me.

Q. Now, isn't it a fact that back in 1982 there was a rate reduction in dialysis? Do you recall that, reduction in the rates?

A. I had nothing to do with this program.

Q. I'm sorry, it was in 1983?

A. Well——

Q. Are you aware of that?

A. I'm aware there have been a series of rate reductions since 1980, yes. But which dates and which amounts, I'm not aware of that.

Q. Are you aware of the amount of reuse prior to that reduction?

A. Yes, certainly. I testified to that.

Q. What was that rate?

A. My recollection at that point is that prior to 1981 about 15 percent of the centers were reusing, and now it's about 60 percent or 63 percent.

Q. And that's since the rate reduction, isn't that right, in 1983?

A. That's certainly since the rate reduction.

Q. Would it be reasonabale then for one to conclude that the rate reduction in 1983 in all probability had some impact on the increase of reuse? Would that be a reasonable conclusion, Dr. Marshall?

A. It would be a reasonable conclusion. But there are other reasonable conclusions as well. We know also that from 1981 the price of a new unit has fallen. We know that there have been major——

Q. We're talking about since 1983, not 1981?

A. We're talking about there have been major changes in how hospitals operate and how Medicare reimburses for a whole range of things. We're talking about an industry that is in great flux right now, that is making new arrangements, that is looking for ways to do things differently.

And I—you know, while the Health Care Financing Administration obviously has an important impact on health policy in this country, I think it's possible to overestimate what HCFA is doing. For example——

Q. Nonetheless——

A. For example, for example, everyone is going around saying that hospital occupancy has fallen off and this is because of prospective payment——

Q. Please, Dr. Marshall, would you stay with the subject.

A. I'm trying to.

Q. Because if you don't, if we continue this way to get off on other tangents, we'll be here very late tonight.

A. I'm simply trying to point out there are different interpretations to these facts than you are trying to give.

Q. We understand that. Nonetheless you have agreed, have you not, that the reduction in 1983 in the——

A. No; I have not agreed to that. Because I don't know.

Q. You don't think it's likely that there was some impact?

A. I am willing to say that it's possible there was some impact. I'm willing to say that it's possible there was some relationship. But I'm not prepared to specify what it was. Because I don't know. I have not reviewed those facts if in fact anyone has collected them and analyzed them.

Q. So to take it then to the present time, do you think it's possible that the rate reduction that's going to take place on October 1 will further reduce—of course it's going to reduce the reimbursement rate, but will further encourage increase in reuse? Do you think that's a logical extension?

A. I think it's a possibility. But I am not willing to make a prediction that it will definitely happen because I don't know.

Q. And if it does happen, do you think that will be good?

A. I think it will be acceptable. I won't say that it's good, but I won't say that it's bad. I think it will be acceptable if that reuse is carried out under conditions of appropriate reprocessing.

Q. Would you put a small I or capital I on the word if, Dr. Marshall?

A. I would emphasize the if. I think that's an absolute—that's an imperative.

Mr. Michie. OK. Let's take a five-minute recess. Are you ready?

The Witness. If you are, I am.

[Short recess.]

By Mr. Michie.

Q. Now, getting back to that item No. 2 in that memo to Mr. Rickard, the last sentence of that item——

A. The one from Anne Desmond?

Q. Yes?

A. All right.

Q. Therefore, John Marshall reaches the conclusion that reuse is a health hazard, it could put the HCFA folks in a quandary. Now, is that accurate? If you in fact reached the conclusion in your assessment report that there was indeed a health hazard, would that have created a problem for HCFA in publishing its regulation?

A. Well, it would have created a quandary for people out there who were reusing and——

Q. What about HCFA? That's what the question begs?

A. I don't know if it would have put them in a quandary or not.

Q. You don't think it would have been difficult for them to go forward with that particular regulation if in fact certain individuals, certain quarters in this—associated with this issue believed that the rate reduction would have encouraged an increase in reuse?

A. Well, I didn't—I don't—reducing the rate of reimbursement is never popular. So would this have made it less popular? Yes. Put them in a quandary, I don't know. It's her language.

Q. I think——

A. Are you asking me would it have made it more difficult to allow HCFA to make this regulation? The answer obviously is yes.

Q. It would have been more difficult?

A. The community would have been probably been somewhat more upset. But they were already going to be upset, so it's the base line that we're talking about.

Q. But even so, do you agree with that statement? Do you agree with this statement? Is that a logical statement for someone to reach?

A. Do I agree that if I said reuse was a health hazard, would it have put HCFA in a quandary? Yes, it would. Furthermore, it would put the dialysis community in a quandary. It would cause an enormous uprise from the patients being dialyzed. And that would have been a much bigger quandary than the implications from Health Care Financing proposed regulations.

Q. Did you satisfy HCFA's concerns about this potential difficulty and provide that agency with a memo that did not address the health hazards of reuse; did you do that?

A. Did I do that? No; I didn't do that.

Q. You didn't?

A. No.

Q. Let me share with you now a copy of your August 6 cover memo to Dr. Windom under which you transmitted the assessment report.

A. Uh-huh.

Q. I also have for you to look at here a copy of Dr. Windom's August 11 cover memo under which he transmitted the assessment report to Dr. Roper.

A. Yes.

Q. Administrator of HCFA?

A. Uh-huh.

Q. Now, both of these memos are only one page in length; is that correct?

A. That's correct.

Q. But there are statements contained in Dr. Windom's memo to Dr. Roper that do not appear in your earlier memo to Dr. Windom. For example, in the second par photograph to Dr. Windom's memo to Dr. Roper it states, quote:

"The findings to date indicate when physicians and facilities exercise appropriate quality control over reprocessing of dialyzers"—and I'm skipping a few words but let me know if I take anything out of context—"patient outcomes appear to be no different in facilities that reuse dialyzers than for those facilities where single use is the normal operating mode."

Now, my question is, Is this statement included in your August 6 cover memo to Dr. Windom? Can you find that statement anywhere in your August 6 memo?

A. No.

Q. Can you show us where this statement can be found in the findings and conclusions of the assessment report itself? And we'll provide you a copy of that now. I think you'll find that the findings and conclusions begin on page 53. And I'd like you if you can to show us where in these findings and conclusions that statement was made.

A. I presume that since you're asking me the questions, it does not. But I will take a moment to look at it to see if it does. But it doesn't surprise me that it doesn't because these were not all written by the same person.

Q. Please, take your time.

A. All right. Now, what was your question?

Q. Can you find in the findings and conclusions the statement that I just read to you from the August 11 memo?

A. No; I cannot find it in those exact words.

Q. Now, can you tell me why—let's go back to the August 6 cover memo.

A. Uh-huh.

Q. Why does this statement appear in the August 11 memo signed by Dr. Windom but doesn't appear in the August 6 memo that you sent to Dr. Windom? Why is that?

A. Because they were written by different people for different purposes. The memo that I sent to Dr. Windom is a memorandum that was written to address what the issues were for the Public Health Service. The memorandum that was transmitted from Dr. Windom to Dr. Roper was an attempt in that middle paragraph to summarize what our finding had been for him. And it was written for that purpose.

Q. Well, isn't that precisely the purpose of the August 6 memo to Dr. Windom? Don't you also try to summarize the findings in that paragraph No. 2 especially?

A. Well, as far as I'm concerned those two paragraphs are interchangeable. I mean we could have—we could have—this paragraph could have appeared here. And this paragraph could have appeared here [indicating].

Q. Are you saying that those two paragraphs say the same thing, Dr. Marshall?

A. They reach the same conclusion.

Q. Is that right; is that what your understanding is?

A. Yeah.

Q. Now——

A. And I would say that I did have an opportunity to review this. And I dare say that if you found the—what we call the yellow box copy of this, you probably will find my initials on it.

Q. So what you're saying then is that there's no difference at all in what was conveyed to Dr. Windom by you in comparison to what was conveyed by Dr. Windom to Dr. Roper; is that correct?

A. I'm saying that we reached the same conclusion. And that conclusion, which I would summarize, is that there is no evidence when reprocessing is properly carried out that it is a hazardous procedure.

Q. But that isn't what you stated in your memo to Dr. Windom. You didn't tell him that it was without hazard; did you? Read that sentence where the word "hazard" appears if you would please.

A. I said that we won't find evidence that it's as safe as having your toe nails cut.

Q. Please read the sentence.

A. I said—well, the current evidence does not show it is without hazard, neither does it demonstrate sufficient grounds to end reuse.

Q. Show me where that statement is made in the memo that Dr. Windom sent to Dr. Roper?

A. That statement is made in there. It's said differently here than what it was said here. That's all. That's what happens when different people write something. Different people have different ways of expressing the same situation. That's why, you know, some literature is very good and some is mediocre.

Q. Can you explain why—I should say can you explain how Dr. Windom in his memo was able to state that, make that statement that I just read into the record, when in fact nothing like that is contained in the findings and conclusions? How could he have reached that?

A. He could reach that because he's a physician and he had an opportunity, and other people had an opportunity, to read what was found there. And there are a variety of ways that you can state those findings and conclusions, OK. The paragraph in my August 6 memorandum is one that I wrote. And Dr. Carter helped me edit, and we made some revisions in it. And we arrived at what we thought was a pretty reasonable statement.

The paragraph in the August 11 memorandum had the benefit of people who had other experiences and other knowledge. And I think that if you were to ask me which of these is the better statement of—that sums up in its entirety, I would put my money on this August 11 statement. I think that that's the more accurate and better and enduring and comprehensive statement of what's in here.

We come here from findings and conclusions that were written by Erlichman and Carter to something that was written by—went through revisions with the benefit of the knowledge and experience of other people. And like anything else, it got better as more people had an opportunity to input it.

Q. This August 11 memo——

A. I don't believe I said that, to input it.

Q. I'm sure Dr. Windom will appreciate your editorial comment. This August 11 memo to Dr. Roper also contains the following statement, quote:

> Absence of reported increases in the morbidity and mortality given increased practiced of reuse suggests that virtually all facilities are following adequate procedures.

A. Uh-huh.

Q. Now, is this statement included in your August 6 cover memo to Dr. Windom? Can you find that anywhere in there?

A. There's a similar statement in there. Let me see if I can find it—no, I guess it was not in there. Maybe it was in the findings and conclusions. Somewhere I used the phrase "isolated instances."

Q. Please check the findings and conclusions and see if you can find that statement which ends with the phrase——

A. I doubt if I will find that original thing. It's a question whether that thought is in there.

Q. [Continuing.] "that virtually all facilities are following adequate procedures."

A. That statement is not in there in those exact words. It's there by inference though in the statement that we have made—when we talked about that the problems encountered under the first findings, that the problem encountered, especially those that involve infectious complications are due either to the lack of protocols or reprocessors are not adhering to their own protocols or following them incorrectly.

But regardless of whether it's there or isn't there, the fact remains that there are probably well over 100,000 reuses that occur every week in this country and there are a very small number of reported complications.

Q. And why is that, Dr. Marshall?

A. So if that statement is not in here, it's a statement that is nevertheless supportable I think based on other knowledge that we have.

Q. Why is it that there are so few reports, Dr. Marshall? Could it be possible because there is no compulsory reporting, there is no requirement for reporting? Could that be one reason?

A. It could be. But there's an even greater probability it's because they're not occurring.

Q. I'd like you to turn to page 28 of the assessment report.

A. Uh-huh.

Q. First to page 26 if you would please, page 26. You're going to find on page 26 at the bottom of the page the paragraph reads:

> CDC survey data, however, for the period from 1976 to the present does not show an association between reuse of hemodialyzers and increased risk of endotoxemia. The sensitivity of this surveillance system, the same one used to determine the instance of hepatitis, has not been assessed by the CDC.

Now, if you will turn to page 28, you will find on that page under the heading of "Bacteremia," middle of that paragraph:

> Because CDC has not included in their surveillance activity any specific questions dealing with increased rates of bacteremia associated with the reuse of hemodialyzers, there is no data covering this potential hazard on a national basis.

Do you read that, Dr. Marshall?

A. Uh-huh.

Q. Now, doesn't that indicate to you that at the present time the CDC does not have a validated data base nor does it even begin to have a complete data base that could reflect accurately the incidence of infection in the clinics? Isn't that the case?

A. Now—no. I do not draw that conclusion from the issues that you have cited to me.

Q. You don't?

A. And let me try to respond to that. In the first place, what we are talking about here is a quotation that is a quotation from a publication of someone named N.J. Peterson, which was made at a workshop on reuse of consumables in hemodialysis in 1982. So it refers to what the situation was in 1982, not to what the situation is currently.

Q. Would it surprise you to know, Dr. Marshall, that a couple of days ago, Dr. John Murphy, who is very well acquainted with that data base, sat here and testified under oath that those statements indeed are accurate today? Would that surprise you?

A. No, that wouldn't surprise me. But that's not the question that you just put to me. And that's—whatever Dr. Murphy has testified to I'm sure is correct and accurate to the best of Dr. Murphy's knowledge.

Q. So if it is——

A. And if the question to me is does CDC have a registry that includes a report from every dialysis center for every patient and that includes every possible complication that could have occurred, I will say to you, no, CDC does not have such a system.

Q. That's not what's stated in this report, Dr. Marshall. Dr. Marshall, the report is specific in stating—and that was confirmed a few days by Dr. Murphy here in sworn testimony—that that data base is not validated; and second, it does not reflect the true incident of infection—would you get me the July?

Mr. RISEBERG. You're not asking a question based on Dr. Murphy's testimony, are you? Because we'd like a copy of exactly what he said.

Mr. MICHIE. Dr. Marshall has suggested that this material, that this statement in his own assessment report, is outdated. What I'm trying to do is to inform the witness through questions that in fact just a few days ago—and I think you were sitting here, right here at the time; were you not?

Mr. RISEBERG. I'd like to see exactly what Dr. Murphy said.

Mr. MICHIE. We'd have an opportunity to do that. But are you challenging what I'm saying now?

Mr. RISEBERG. I'm simply saying that we would like to see what Dr. Murphy said exactly before we could base a question on some characterization of what may be his view.

By Mr. MICHIE.

Q. Perhaps maybe this would help you, Dr. Marshall. I have here a July 8, 1986 memo that was written by Dr. Solomon and Dr. Murphy, both of CDC, and addressed to Dr. Hughes, their superior at CDC. And if you will turn to page 2 of that memo under "Summary," it states——

Mr. RISEBERG. You said that was a draft memo?

Mr. MICHIE. I did not say that.

The WITNESS. It's certainly not a final because it still has—but anyway, go ahead.

By Mr. MICHIE.

Q. It states:

> It is evident that the data base concerning the safety and appropriateness of reusing disposable hemodialyzers is currently inadequate to make a scientific assessment of whether or not this practice should be promoted, tolerated, or prohibited for public health purposes. Even if the practice itself is found to be safe or even beneficial, there is an obvious need for standards addressing the manner in which reuse is performed. Such standards must be based on clinical trials and incorporate long-term assessments of patient outcomes using a variety of measures including morbidity and mortality.

This memo is dated July 8, 1986. So my question to you now is the statement that's made, the second statement that I read to you from the August 11 memo, the absence of reported increases in the morbidity and mortality given increased practice of reuse suggests that virtually all facilities are following adequate procedure. Is that an accurate statement?

A. That is an accurate statement.

Q. That is an accurate statement?

A. That is an accurate statement.

Q. And what do you base your opinion as it being an accurate statement, what do you base that on?

A. I base my opinion on the fact that physicians and surgeons in this country are responsible people, and when they notice that there is a problem with a medical procedure, they tend to communicate that to medical journals, they tend to communicate that to their peers, and the system tends to respond to that and things get fixed. And that's particularly true in something like this where you have patients being treated with the same procedure in a group situation, there are lots of patients.

It's hard to see those things when you're talking about one practitioner off in West Pistol Grip seeing patterns in his or her practice. But when you're talking about people in a clinic, believe me, the clinic staff starts to talk if there's a consistent complication that appears——

Q. How do you know this, Dr. Marshall?

A. I know that because I know how medical practice works.

Q. Are you a medical doctor?

A. I am not a medical doctor. And that's not what's at issue. And I am an expert in how health care is delivered, and in this area and I have spent time reading research reports and talking to people about how it works.

Q. Isn't it the case that because of the fact, as both Dr. Murphy and Dr. Solomon have stated in this memo dated July 8, 1986, that the data base, the data base at CDC is inadequate to make any determination whatsoever about reuse, that's No. 1? And No. 2, isn't it the case that FDA doesn't require reporting, and so therefore because of the fact there is no mandatory reporting, no one, but no one, not at FDA, not at CDC, not even you, can say for certain what's happening out there in the clinic? Isn't that the case?

A. I would agree that no one can say with detailed certainty what it is that's happening in clinics.

Q. What about with any certainty?

A. I can say with any certainty that if there were major problems, that would be known, that would be being discussed in the literature, that would be being discussed at conferences, shared with our staff by practicing nephrologists and practicing kidney specialists out there. That's what I'm saying. That would be reflected in the kind of billings that HCFA is getting for complication rates. And none of that has been taking place.

Now—let me continue.

Q. Please, go ahead.

A. Dr. Murphy and Dr. Solomon are, I'm sure, very sound in what they are saying here. But they are talking about standards of science, they are talking about standards of publications, they are talking about the kind of data you'd like to have to be able to explain away all of the variance in the system.

Q. That's an assumption on your part?

A. You're making assumptions about what they mean. Why can't I?

Q. I only read what they wrote, Dr. Marshall.

A. I'm only trying to create a context. I don't know why they wrote what they wrote.

Q. May I suggest that for your own satisfaction that when this proceeding is over with that you get on the telephone and call these two epidemiologists?

A. I appreciate the suggestion, thank you.

Q. And ask them what they meant.

A. I appreciate the suggestion. But the facts are that this document is this document, and this document is a different document, and each of these are different documents.

Q. Oh, indeed they are, Dr. Marshall. I think everyone here would agree with that.

Again, I will ask you the statement that I read, the second statement that I read from the August 11 memo, is this a true and accurate statement based upon the assessment findings as well as on the findings that the FDA's recently completed dialysis clinics surveys and on the CDC's findings and investigations of five dialysis clinics in May, June, and July of this year?

A. Yes.

Q. It is?

A. It is.

Q. So, in other words, what you're stating is that the findings with extremely poor process and procedure in these clinics by the CDC, the findings of infection outbreaks within these clinics, the findings in the FDA's recently completed dialysis clinic surveys, which as you may know confirm the findings of the CDC in their recent inspections, in despite of all of this, you still say that the statement, "virtually all facilities are following adequate procedures," is accurate and true? Is that what your statement is?

A. Well, my statement is that I believe that virtually all facilities are following effective reprocessing. I am not agreeing with your statement that that is in spite of all of this alleged evidence to the contrary that you're citing. Because I don't think that the CDC did more than look at some isolated citings. I think that the FDA report is a survey report of what people in offices who were responsible for programs in States say is their impression of what's happening out there and from some rather rudimentary kinds of surveys.

But even those do not show that there are problems. They're showing that people may not be following this process——

Q. Dr. Marshall, have you read the survey reports from the District of Columbia and California?

A. I have not read them in detail.

Q. So you don't know what's in them; do you?

A. I have been assured by staff that they say what they say here. And I have been assured by staff that these statements are appropriate statements.

Q. Has your staff told you that whatever was written in these survey reports from the District of Columbia and California was inconsequential? Is that what they told you?

A. I didn't tell you it was inconsequential. I said they told me there's nothing in there that made these statements in either the second paragraph in my memorandum of August 6 or in the second paragraph of the memo from Dr. Windom to Dr. Roper on August 11 that were inaccurate.

Q. When did they tell you this?

A. Dr. Carter told me this when I showed him this draft before I sent it to Dr. Windom. Dr. Carter told me this when I got a copy of Dr. Windom's memorandum back. And I said, you know, is this OK?

Q. And he said it's accurate? Is that what he told you?

A. That's what he said.

Q. Do you recall when he told you that?

A. No, I don't recall the exact date.

Q. Have you read—you may recall that on August 11, the very same date of that memo from Dr. Windom to Dr. Roper—do you recall on August 11 having received from the CDC a rather substantial amount of documents relating to Dr. Murphy's work and Dr. Solomon's work? Do you recall that?

A. No. I don't.

Q. Do you know whether or not those files were reposited over at OHTA? Do you know that?

A. They probably were.

Q. Have you not read any of them?

A. No, I haven't.

Q. Are you aware that this particular memo that I read from was that from that collection of documents?

A. It wouldn't surprise me if they were.

Q. Did anyone on your staff apprise you of this document over the last couple of weeks?

A. I don't recall.

Q. Didn't you draft——

A. They certainly did not apprise me of that before either August 11 or August 6.

Q. Well, they couldn't have; isn't that right?

A. Pardon?

Q. They couldn't have? Because they didn't get the documents until——

A. And furthermore having read it now, I still say that this is accurate. And I still stand on these two paragraphs.

Q. But you still haven't gone——

A. Because that's Murphy's and Solomon's view of the world.

Q. But you still haven't gone through the documents from CDC; have you?

A. I don't know whether the staff has or not. I presume they have. I have not, no.

Q. Isn't it possible then that there is something in those documents, large stack of documents from CDC as well as a large stack of documents that you received on the same date from FDA and elsewhere in the Department, isn't it possible that some of those materials would perhaps shed some light as to whether or not that's an accurate statement in the memo, the August 11 memo?

A. Well, certainly it's possible. It would be irrational to deny that it was possible. I don't think that there is anyting in there that would call for a major change in these. Because if there were, either Dr. Carter or Mr. Erlichman would have brought that to my attention.

Q. Didn't you draft the memo for Dr. Windom's signature, the August 11 memo? Didn't you draft that?

A. I did the initial draft.

Q. You did?

A. It went through a number of revisions, as you know.

Q. How many revisions did it go through, Dr. Marshall?

A. I don't know.

Q. We're going to give you a copy of the memo.

A. Of the yellow box?

Q. No. This is just black and white, no yellow.

A. Oh, OK. oh, my goodness.

Q. If you'll look at the bottom of the page the notations indicated, of course, that you prepared the memo.

A. Uh-huh.

Q. And no less than 10 other individuals from FDA, CDC, NIH, and the Office of the Assistant Secretary for Health, including Dr. Mason, Director of CDC, and Dr. Windom himself, further these notations indicate an interagency meeting on August 8 concerning this memo; isn't that correct?

A. Uh-huh.

Q. Was this not an extraordinary procedure for so many people including the chief counsel for the PHS, Mr. Riseberg, and Dr. Mason, to be involved in revising and finalizing a one-page cover memo? Isn't that extraordinary?

A. Unfortunately it's not.

Q. You wouldn't say that this is extraordinary?

A. Well, I mean it depends on the definition of extraordinary. Letters for signature by higher officials are frequently reviewed and revised and revised and revised. So would I say that for a letter for the Assistant Secretary's signature, the Secretary's signature, to have a half dozen or more revisions between the time when one person writes it and it's signed off at that level is not extraordinary? No.

Q. But people in four agencies?

A. That's very often what happens. Because if it's a cross-cutting issue, it requires that.

Q. Give me a couple of examples, Dr. Marshall. I'm sure you can recall them since you're so confident that this isn't extraordinary. Give me a couple of examples.

A. Sure. The routine congressional correspondence, I bet if you went back and——

Q. We're not talking about that.

A. On any of these replies to Senator Heinz you will find that they were revised a number of times.

Q. We're not talking about a congressional letter. We're talking about a one-page memo of transmittal from Dr. Windom to Dr. Roper. And I'm asking you why would you have to have a meeting, why would there have to be 10 individuals besides yourself involved in revising this memo? Why would Dr. Mason, who's located all the way down in Atlanta, have to become involved in the revising of this one-page memo? That's what I mean when I ask you is this not extraordinary.

A. It's a little bit out of the ordinary——

Q. A little bit?

A. [Continuing.] Because in part this is a process that was carried out differently from how we normally proceed. Normally if I were to send a memorandum to the Assistant Secretary for Health that involved the activities of the Centers for Disease Control, NIH, FDA, whatever, I would not have sent that to that person unless I had—unless I had cleared it with my counterparts at that level. I would not send a memo to my boss, who happens to be Dr. Wyngaarden's boss, unless I discussed it with Dr. Wyngaarden.

In this situation because of the timing of things——

Q. What do you mean by the timing of things?

A. Because I wanted to be certain that Dr. Windom got my August 6 memorandum promptly, the day I sent it to him, the day the assessment was finished. And I wanted him to have it before it was—before he read about it in the New York Times or the Washington Post or one of the sheets that gets circulated. I did not follow that normal process of clearing it by the agencies. That was something that I did with a lot of careful thought because I work with those gentlemen day in and day out——

Q. What were you concerned about? What was the extraordinary procedure? What were you concerned about?

A. I didn't want him getting a phone call from a reporter asking him questions about it before he ever got it from me.

Q. Or maybe perhaps from someone on the staff here at the committee?

A. Or from someone at the staff at the committee. I wanted him to have the benefit of having it directly. And I wanted him to have it without getting a lot of comments from other people within the Public Health Service. And having done that, though, I wanted to be certain—I mean that's all right for me to do that with something I give him. That's me to him. And if that's wrong, then I'm on the line.

But when you're talking to something he's sending out to HCFA as a PHS position, then it's incumbent on you to make certain that it reflects the judgment and responsibilities of the other people for whom you're speaking. So I don't think it was extraordinary to have these people personally involved in looking at it.

And I also wanted to be clear for the record that Dr. Mason did not come from Atlanta for this purpose. He was in Washington for the agency heads meeting.

Q. I didn't suggest that.

A. Oh, yes, you did suggest that.

Q. I assumed he remained in Atlanta. But it was sent to him; wasn't it him?

A. I think that was true for the August 8 discussion. But on August 11 he was here.

Q. Again I'll ask you: Can you explain why this one-page memo was so important to have deserved and received such a high level of review and scrutiny by so many people from four different agencies?

A. And my answer is it was because I had made statements in an earlier memo about those agencies and about their cooperation with this process. We were transmitting this as a Public Health Service position to the Health Care Financing Administration, and it's incumbent on you when you're doing that to make sure that the very top people who you're committing to do things have a chance to look at it and say, yeah, that's OK, it's scientifically and clinically accurate, and that represents a scientific consensus of the people who were responsible for providing executive direction to the agencies of the U.S. Public Health Service.

So I don't think it was extraordinary for this situation.

Q. But isn't it the case that the importance of this memo was also linked to HCFA's intention to publish 4 days later on August 15, its final regulation to reduce dialysis reimbursement rates?

A. I can't speak to how close that link was because I was—I was not party to any discussions and I don't think there were any discussions within the Public Health Service about that.

Q. But you don't know?

A. That's right, I don't know. But I would also say that certainly if I were the Administrator of HCFA, I would want to know what the Public Health Service's view was of this before I came out with any kind of a regulation even if it was a regulation that was going to double the reimbursement rate.

Q. And wasn't the deadline of August 6 tied to HCFA's intention to publish on August 15?

A. No. The deadline of August—there was no deadline of August 6. There was a deadline of August 10, which I unilaterally moved——

Q. Fine. Was that deadline of August 10, in any way connected with HCFA's intention to publish on August 15?

A. No. The deadline of August 10——

Q. Thank you.

A. [Continuing.] Was an extension of April 10, when he published——

Q. You answered.

A. I want it to be on the record, of April 10, June 10, July 10, and August 10. I won't go into all of the details as to why we had each of those extensions, but it was a simple chronological extension of the 30 days.

Q. So what you're saying is that the deadline for August 10 had no connection whatsoever with the August 15 publication date for HCFA's regulations to reduce the reimbursement rates? Is that your testimony?

A. That's right, it was merely coincidental.

Q. The two sentences in the memorandum to Dr. Roper that we went over a little earlier, were these not to accommodate the needs of HCFA and provide HCFA justification to go forward with the dialysis reimbursement rate reduction?

A. No. They were intended to communicate a copy of this document to the administrator of HCFA.

Q. Do you recall having a somewhat heated or spirited discussion with Dr. Carter on either August 7 or August 8 concerning the content of the memo you drafted for Dr. Windom that was forwarded to Dr. Roper on August 11? Do you remember such a discussion?

A. No. And I seriously doubt that any such discussion would have occurred.

Q. You don't recall any such discussion between you and Dr. Carter on August 7, or August 8?

A. No. Because the facts of the matter are that on August 7, I was scheduled to be on annual leave. And I received a telephone call from Bruce Artim at home, before I left to conduct some personal business that day, saying that he would like to have me draft a memorandum for Dr. Windom to use in transmitting this memo to Dr. Roper. And I banged out a draft of that on my PC at home and dropped it off to Mr. Artim on my way over to Annapolis.

Q. On August 7?

A. On August 7.

Q. Why was there a need—can you explain to me why was there a need for another memo? Why couldn't they just have sent the same text, perhaps with a change of a few words of the memo that you sent to Dr. Windom on August 6?

A. Because, as I've explained, the purpose of it was different. This is to transmit something to Dr. Roper, and it wasn't—it had to do with summarizing the findings, it didn't have to do with the information that was in my August 6 transmittal.

Q. Which didn't have to do with summarizing the findings?

A. The memo to Roper was simply summarizing the findings. My memo to Dr. Windom was to summarize the findings and to indicate to Dr. Windom what my process—why I hadn't cleared with the other agencies——

Q. The second reason, I understand that. But that could have just been left off. Why couldn't you have put in the second paragraph in your August 6 memo? Why couldn't that have served as a second paragraph in the August 11 memo?

A. Well, I think probably the real reason why, other than that I have an aversion to cutting and pasting, the real reason was because I was at home and didn't have a copy of this. Any I didn't, you know, remember what I said. So I wrote something that I thought said——

Q. You wrote something different?

A. I wrote something that I thought said the same thing. And I have said that I see these as interchangeable. Although given a preference for which of these is more polished, I'd say the more polished one is the one from Windom to Roper, as well it should be. It had the benefit of all of these revisions that we've been discussing.

Q. You're saying it was a more polished one, but you're saying you didn't have a copy of the other one to go by. You just sort of wanged it off——

A. I PC'd it off. I don't have a Wang at home. You asked me why it was different, why didn't we just send the one I sent to Windom? And I said it was different because when I was asked to send a transmittal letter, I didn't have a copy of it in front of me. So I sat down at my word processor and wrote what I remembered.

Q. Didn't you have it on the 8th? Were you not in your——

A. I had already turned it in on the 7th.

Q. But it didn't go until the 11th; did it?

A. That's right.

Q. Didn't you have a copy of the other one on the **8th** when you were in your office?

A. No; it was—all these people were revising it on the 8th.

Q. But you still had a copy of it, you were responsible for preparing it; weren't you?

A. No; I didn't, I didn't have a copy of it.

Q. You had no copy of it at all?

A. I didn't have a copy of it.

Q. How did you get a hold of this then?

A. You requested it, and I had a copy made.

Q. So in other words, what you're saying is you made one copy of your first draft——

A. I made a copy of it, I printed out one copy. I kept it on a floppy disk at home. I took that copy down and dropped it off with Mr. Artim, OK, and that was the last I knew of it until——

Q. Until what?

A. Until the 11th I suppose.

Q. You suppose?

A. Yeah.

Q. But you're not certain?

A. No. I had involvement with it on the 8th. Because on the 8th—I was not at the meeting on the 8th, this August 8, 1986, meeting with NIA, C.C. Eccleston, and Mr. Riseberg.

Q. This Mr. Riseberg sitting right here?

A. The very same.

Mr. Riseberg. I do hope this is all leading to some important point. Because it sounds to me as though we are discussing some detail that——

Mr. Michie. Bear with us, Mr. Riseberg.

Mr. Riseberg. I certainly hope so.

Mr. Michie. Bear with us. Mr. Riseberg.

The Witness. I was not at that meeting, OK. But I did have a telephone conversation with the principals to that meeting afterward. They called me at some point during the meeting. But the next time I actually saw a draft of the letter was on the 11th of August at the agency head meetings.

By Mr. Michie.

Q. We just handed you a copy of a document, an undated document, that was sent to the committee along with a collection of other documents from the Department?

A. Right.

Q. And you note that at the top I wrote in long hand "first draft."

A. Right.

Q. What I should have done is I should have put a question mark there. Because of course I wasn't able to ask you whether in fact this was the first draft until now. Was it?

A. It was a first draft.

Q. Is that it?

A. Uh-huh.

Q. Did you share this first draft with Dr. Carter on the 7th of August?

A. I don't believe so.

Q. Did you discuss with Dr. Carter at all this first draft?

A. I don't know whether I did or not. I discussed probably the 11th draft. And I may have, but I don't remember whether I did or not.

Q. You don't remember? You don't remember, as I put it earlier, either a heated or a rather spirited discussion with Dr. Carter about the contents of your draft memo that was prepared for Dr. Windom's signature? You don't remember that?

A. No.

Q. You don't recall Dr. Carter taking strong issue with those two sentences, those two passages that I read to you?

A. I don't know what——

Q. Because they do appear pretty much the way they did in the final. Why don't you check that draft and see if you can find it.

A. Well, I mean it's not—that's not the issue. The issue is—the question you asked me is did I have a heated discussion with Dr. Carter? And the answer is I don't recall that I did.

And the further answer that I make to you is that, you know, it's hard for me to conclude that I would have had that when I knew that this thing was going to be revised, when I knew it was in the very process of having other people look at it that afternoon—or that day.

Q. Do you have a recollection of not having had any kind of discussion with Dr. Carter either on August 7 or August 8 pertaining to this memo?

A. I can tell you that I definitely did not have a discussion with him on August 7. And I can be fairly certain that I did not have what you have characterized as a heated discussion where he strongly disagreed. Because I will tell you that if Dr. Carter——

Q. Again——

A. If Dr. Carter strongly disagrees with me about something, I almost always do it his way because he's the doctor.

Q. That's not the question I asked. Please respond to the question.

A. The answer is no, I do not recall.

Q. Do you have a definite recollection of not having discussed with Dr. Carter on August 8 the memo, this the contents of the memo?

A. You've changed the question.

Q. That's right, I did.

A. Let me be sure I'm answering the right question. Do I have a recollection I did not discuss it with him at all?

Q. Do you have a definite recollection that you did not discuss this memo with Dr. Carter on August 8?

A. I do not have such a definite recollection. I will say that I did not have a discussion in which he strongly disagreed with words that I had here——

Q. That was not my question.

A. That was your question earlier.

Q. And you answered it.

A. I want to make sure we're clear that I agree I did not have that kind of discussion. I would have had a recollection of that if I had because it's very, very rare if ever that I would override his judgment on a matter like this.

Q. Was Dr. Carter given the opportunity to review the final draft of this memo prior to it being given to Dr. Windom for his signature?

A. I don't recall whether he was or was not. My guess was he was not——

Q. Guess?

A. My assumption is he did not see it. Because he was out in Rockville and this was done down in the Humphrey Building.

Q. Let's go back down in time to July 8, 1986.

A. Yes.

Q. Did you some time during the morning of July 8 meet with Dr. Carter?

Do you recall meeting with Dr. Carter on that morning?

A. Yes; I do.

Q. What was the purpose of this meeting? And what do you recall of that discussion?

A. My purpose was to show him the memo that I was taking down to the meeting with Dr. Windom later that day, and to ask whether he had any comments to make and whether he—ask him whether in his view that was a reasonably accurate summary of what had occurred.

Q. And what did he tell you? Did he offer any suggestion on the memo?

A. He may have made some minor suggestions. But he was basically in agreement with it.

Q. Did you draft that memo?

A. Yes.

Q. You did?

A. Uh-huh.

Q. What was it that prompted you to draft that memo to Dr. Windom?

A. I was going to a meeting with the man who had only recently come on board as the Assistant Secretary for Health. It was going to be a meeting that I thought would involve some rather spirited discussion.

And it was a meeting that was going to address a complicated issue that he was being introduced to for the first time, an issue that went back some half dozen or almost 8 years. And I wanted to have a discussion document that he could follow along with the discussion, so we would help keep this as a very focused kind of discussion. It was to be the first substantive meeting with a lot of people that I'd had with him, and I wanted to make sure that it was a productive meeting that didn't get off on some tangent.

I did not know what kind of person he would have to do staff work at that time, so I wanted to create a structured discussion. And that's why I wrote that memo.

Q. Wasn't your purpose to—at that time wasn't your purpose to with this new, this brand new Assistant Secretary for Health, to make a clean breast of activities, to inform him of your concerns with regard to what is happening?

A. Well, it certainly involved——

Q. And what had happened?

A. It certainly involved a desire to alert him to the fact that we were going to issue a report that would contain recommendations that would not be enthusiastically received necessarily by the other agencies, and that it was not totally consistent with my testimony on the 6th of March.

Q. Going back though——

A. So it was a meeting, and it was going to be a discussion where I wasn't bringing him real good news. I mean, you know, if you're newly arrived at an organization, I think you'd prefer to find that this is an organization where eveything goes well, where there are no frictions, no dissensions, happiness and bluebirds singing.

So, here we are on his second day on the job coming in saying, "Hey, I've got this pile of stuff here and it's going to be a problem for you, we're going to add this to your problem queue."

Q. How long had he been Assistant Secretary for Health when that meeting was held?

A. I think it was his second day on the job. I think he started on a Monday and that was a Tuesday.

Q. Does that mean that Dr. Macdonald was on the job the week prior? Was he still acting the week prior?

A. Uh-huh; yeah. And I chose not to go to Dr. Macdonald with it. Because I knew he was coming to an end, and I thought that was something we might as well start with the new man.

Q. Could it also have been too that—that you felt that perhaps it would be—how should I put it? That it would be perhaps more advantageous for you to wait to give this bad news—you knew that Dr. Windom was coming on, to give this bad news, to give these particular issues, to the person who would ultimately make the decisions on what to do about this bad news? Was that also on your mind at the time?

A. Well, I agree with the second part of what you said. I don't agree with I thought it was to my advantage. I didn't see any advantage to anybody. But I mean, yes, he was going to be responsible. Dr. Macdonald was interim, he was—he wanted to go back and run the Alcohol, Drug Abuse & Mental Health Administration. So there wasn't any point in my telling him about it.

Q. When did you come to feeling, when did you come to have the feelings, that you express in that July 8 memo? Was it a week before July 8? Was it 2 weeks? How long did you wait? You know, of course, that a new Assistant Secretary was coming on. But how long had you harbored your beliefs, as well as your concerns, that were expressed in this memo?

A. Well, I think that I began to have some sense of the reticence of some of our colleagues about the time we received the material from the committee on the 9th—7th or 9th of June. And I think that my concern probably escalated somewhat several weeks later with the MMWR report from NIOSH on formaldehyde on the reprocessing.

And then, it certainly got to the point where I realized that it was now going to be a matter that needed to be resolved with the Assistant Secretary for Health when the MMWR reported its recommendations on the need for further study.

So that those recommendations were really what drove me to say we better have a meeting, and we better have all the principals there, and we better find out where we're going and decide what steps we're going to take and resolve this issue. And there was probably a week in there when we could have had that meeting. But I decided to defer it, because there was no point in getting Dr. Macdonald cranked up when on a Friday he was going to go off and out of town.

So I decided to wait and have it early on Dr. Windom's agenda, which is not the behavior I would have engaged in if I were preoccupied with heading off these August 11 regulations.

Q. Let me——

A. I would have asked for a 90-day delay.

Q. Let me digress for a moment and take you back to the dates of August 7 and 8. Does anyone have a calendar here?

A. The 7th was a Thursday and the 8th was a Friday.

Q. Do you have your calendar?

A. Uh-huh.

Q. Would you mind looking at your entries on August 8 to see if there's anything there.

A. There is no entry on my calendar at all for the 8th of August.

Q. None at all? What about your secretary's calendar?

A. This is hers. This is what I brought, because this is more detailed.

Q. So August 8 was a Friday?

A. August 8 was a Friday.

Q. Now, let's cover the period from August 4, which is what day of the week, August 4?

A. August 4 was a Tuesday.

Q. A Tuesday——

A. No, August 4 was a Monday.

Q. Was a Monday, right. August 4 through, let's say, August 15.

A. Uh-huh.

Q. Did you and Dr. Carter at any time during that period have a discussion regarding the contents of the August 11 memo that was signed by Dr. Windom and sent to Dr. Roper?

A. Not to my recollection.

Q. Do you have a definite——

A. My calendar—well, I can say definitely that I didn't have any such discussion with Dr. Carter on the 4th or the 5th or the 6th or the 9th.

Q. But if you had you wouldn't have put it in your calendar; would you?

A. The reason I can say that with such certitude, Mr. Michie, is that I wasn't asked to do that memo until the 7th. So I wasn't thinking bout it at all prior to that date.

Q. I understand, I just wanted to——

A. On the 7th I did it at home and went to Annapolis. And I came back to Annapolis—from Annapolis for a meeting. That was at 4 o'clock and was on a completely different issue, downtown, not out in Rockville. And I wouldn't have seen Dr.——

Q. You can say for certainty that you didn't have a discussion with him about this August 11 memo on the 4th, 5th, 6th, and not on the 7th because you weren't there?

A. Right.

Q. But you can't say with certainty that you didn't have a conversation with him or discussion about that memo on the 8th?

A. I may have had one on the 8th.

Q. On the 11th?

A. It's very unlikely I would have had one on the 11th because that was a day I spent downtown.

Q. On the 12th?

A. I'm quite certain I didn't have one on the 12th.

Mr. RISEBERG. What's the date of the memo?

The WITNESS. The 11th.

By Mr. MICHIE.

Q. The 13th?

A. By the 12th or 13th I would have had a copy and said here's what was sent to transmit.

Q. A few seconds ago you did say you may have had a discussion or conversation with Dr. Carter on the 8th; is that correct?

A. I said I may well have. I said I don't recall whether I did or didn't. What I have said is I did not have a heated discussion that was a result of his strong disagreement with it. I want the record to be clear.

Q. I understand. We've clarified that at least a healf dozen times.

Mr. RISEBERG. You asked the question at least a half dozen times.

The WITNESS. Every time you ask it, I want to give you the full and complete answer. I don't want to read an excerpt of this record in the beige sheet that says this is what it says.

Mr. MICHIE. For your information, Dr. Marshall, these transcripts are sealed unless the chairman decides otherwise.

Mr. RISEBERG. That's not the position of the Department. The Department considers Dr. Marshall here on business and will use the transcript in the appropriate means it sees necessary.

Mr. MICHIE. What Dr. Marshall sees fit to do with his testimony is entirely his business. But as far as the committee is concerned, these transcripts are sealed unless and until the chairman decides otherwise. That in no way affects you. If you wish to give your transcript to anyone at all, that's your prerogative.

The WITNESS. Right. About I'm, just saying at some future time when the chairman may or may not decide to unseal them, I just want to make certain when I answer the question several times I give the same answer several times.

Mr. RISEBERG. And I want to make clear from the Department's standpoint, we view the witness as here on official business and that they may be asked to supply their transcripts. That is an option that the Department retains.

By Mr. MICHIE.

Q. The first three sentences of the first paragraph of your July 8 memo to Dr. Windom, if you want to get back to it. Do you have a copy here or do you want to turn to page 544?

A. We can turn to page 544 and get it. Uh-huh.

Q. Quote:

> As HCFA continues to ratchet down the reimbursement rate for hemodialysis, concern has grown on the part of the hemodialysis patient and Congress with respect to the safety and efficacy of the reuse of dialysis equipment, including blood lines, tubing, transducer caps, and filters. Senator Heinz was sharply critical of the Public Health Services role in this issue. Involvement of NCHSR is only recent, but NIH, FDA, and CDC have had a long, noble, productive involvement with these issues.

Dr. Marshall, what did you mean by the statement that NIH, FDA, and CDC had had a long, noble, productive involvement?

A. I meant there was no agreement within those three agencies on who was responsible for carrying out activities.

Q. Activities concerning what?

A. Concerning studies that should be done to ascertain the more full parameters of the safety and effectiveness and what the requirements were for assuring that.

Q. Could you also have been referring at that time to a study that was sponsored and paid for by NIH, entitled "Multiple Use of Hemodialyzers"? Are you aware——

A. You mean later so-called Deane Report?

Q. Yes, are you aware of the controversy surrounding that report?

A. No; I was not referring to that.

Q. You were not?

A. I was referring simply to the interaction between the three agencies, not to what any of them had done. Certainly each of them had done productive things and each of them had carried out certain activities. But there was not a unified Public Health Service approach. They were each operating from their own mission, and in the case of NIH from congressional directive.

Q. Without coordination, without adequate communication?

A. In my opinion there was not even the right way to say it. There was not as much of an attempt to have an integrated Public Health Service type of activity as there should have been.

Q. Did you mean by that that the communications could have been better?

A. No; I meant that the process could have been one that led more to a Public Health Service position than to three separate agency positions. I think that if you asked—well, that is a digression. But it's an important one.

I don't think that most of the people who work for FDA or for NIH or for CDC—it's probably less true for CDC, but certainly NIH or FDA. If you ask them do they work for the Public Health Service, they'd say, no, I work for FDA or NIH. To me the Public Health Service is the aggregate of them.

That represents maybe my view of the word. It's important to me because our responsibility is to reflect a PHS position.

Q. Don't you say in your memo that communications are less than adequate?

A. I said that elsewhere. But you were asking me about that particular sentence.

Q. I understand——

A. I was just trying to respond to that particular sentence.

Q. But elsewhere in the memo you do say that communications were less than adequate; is that right?

A. Yes.

Q. Continuing now with the text in your memo, you go on to state in the last two sentences in the first paragraph:

> As events have unfolded, it is clear that the March 6 testimony was not based on all of the germane facts, and that we may need to take a position counter to that which we argued on March 6. We need to ascertain a PHS position and inform HCFA of that positon so as to minimize embarrassment to the Department.

First, Dr. Marshall, would you identify and elaborate on the events that unfolded and led you to conclude it is clear that the March 6 testimony was not based on all the germane facts. What were you talking about?

A. A, I didn't have access to the draft reports that FDA had in hand from the three State contracts and the District of Columbia. B, I did not have—I was on—as events unfolded, it was unclear to me whether CDC though that 4 percent formaldehyde concentration was the right concentration or not and whether that was an official CDC position or whether that was something that one of their scientists had published in a paper or said at a symposium. And those were I think the two issues that concerned me.

A third issue that concerned me was whether or not the NIH registry really would provide data on this issue of the effects of reuse. And so we were detecting by that point more uncertainty in the informal communications tht we were getting from NIH as to whether or not this really would address these issues. I had said very firmly in the testimony that it would——

Q. Would what?

A. That the registry would permit addressing these questions and doing retrospective study. We were hearing comments in the staff at NIH that, well, maybe it would, maybe it wouldn't. They really hadn't decided how they were going to structure it and what information they were going to get. NIH has subsequently assured us and stated for the record that they would be able to address these, so that concern is less of a concern now.

Now, with respect to the position counter to that which we argued on March 6, what I essentially had in mind there, was I had been firm about the fact that the application of Good Manufacturing Practice Act provisions to reprocessing was probably not appropriate. By July 8, I was less certain about whether that position was right and was moving in the direction of recommending that the good manufacturing practices be applied to this process.

Q. And isn't it also the case that another event that took place was that you learned from your staff that there was indeed a great deal of controversy associated with the NIH-sponsored report, "Multiple Use of Hemodialyzers"——

A. No. I——

Q. Can I finish my question please.

A. Surely.

Q. Was it not the case that this was one of the events simply because the—let me ask you the question: Were you aware of this controversy when you testified on March 6?

A. Absolutely.

Q. Were you?

A. Yes.

Q. Did you not use this study as a cite in order to buttress your case for the safety of reuse? Didn't you use that?

A. I was aware of the controversy, I was aware of the allegations, but I had discounted them. And I had used that testimony and there were no events that unfolded that, as I put it, that would—wouldn't—today I would still use the Deane report.

Q. Was your staff aware of it?

A. Yes.

Q. At that time they were?

A. Oh, yes.

Q. How do you know that?

A. Huh?

Q. How do you know that?

A. Because they told me.

Q. Why did they come here then and express surprise when I showed them the October 9, 1981, report from Dr. Ketteringham, who was vice president of Arthur D. Little, Inc.——

A. I don't know. You'd have to ask that question——

Q. I'm asking you: Do you understand why——

A. That's a little strange because I specifically know—I recall in preparing me for that testimony Dr. Carter pointing out that there was some controversy about this.

Q. During preparation——

A. Yes; that some of the subcontractors had claimed that their findings were not accurately represented by Dr. Deane. And he had looked at that and he assured me that it was still something that we could use.

Q. Are you aware that after the hearing Dr. Carter had a meeting with Dr. Deane in his office?

A. Yes, yes. In fact I had a meeting with Dr. Deane.

Q. Are you aware that——

A. I sat in on part of that meeting.

Q. Are you aware that Dr. Carter, in presenting the charge and complaints of the ADL firm, asked Dr. Deane to refute them?

A. I don't have knowledge of what Dr. Carter did or didn't do on that point. You should ask him that.

Q. Did Dr. Carter ever tell you what the outcome of that meeting was?

A. I'm reasonably certain that he did, but——

Q. Did he ever tell you, for example, that Dr. Deane was unable to refute the complaints and charges of ADL?

A. Well——

Q. Did he ever tell you that?

A. I don't know whether he did or whether he didn't. But if—I don't think that it made any difference to what our report and recommendations are right now. The Deane report was 1979?

Q. No; it was 1981.

A. That was 5 years ago.

Q. But you used it. It's on a page 56 if you want to look at it.

A. Well, yes——

Q. You used it in your testimony to support your contention that reuse was safe?

A. I did.

Q. You didn't mention anything though in your testimony about the controversy?

A. No; I didn't.

Q. And I'll ask you again: Are you certain that at that time you knew about this controversy? And are you certain now that at that time you had read the October 9, 1981, letter from Dr. Ketteringham to Dr. Deane?

A. Well, why don't you ask me those questions one at a time and let me answer them one at a time.

Q. Answer them one at a time.

A. What was the first question?

Q. The first question is, Are you certain at the time prior to your testimony, in preparation of your testimony, that you were fully aware of the controversy surrounding this report?

A. My answer is I was aware of the controversy. I know more about the controversy now than I knew then.

Q. Second question: Were you aware and had you read the complaint and charges of ADL as they were memorialized in a letter dated——

A. I don't know whether I was or was not.

Q. Do you have a definite recollection of not having read them?

A. How can you have a definite recollection of not having read them. You've used this device several times.

Q. I'm only trying to get a clear answer from you.

A. It is psychologically impossible to have a clear recollection of something that you don't recollect.

Q. So you don't recall ever having read this letter?

A. I said I don't know whether I did or whether I didn't.

Q. You don't. And do you recall having read the letter since then, since the preparation of your testimony?

A. I've read the letter at some point in time.

Q. When did you read the letter?

A. I don't know, I don't know whether it was before or when it was.

Q. It may have been before, it may have been after?

A. Yes.

Q. You are certain that you knew there was controversy prior to your testimony?

A. I knew there was controversy; yes.

Q. Could your statement about events unfolding, could that also have included your having received from Senator Heinz on June 9 a large collection of documents, including PHS documents, some of which you had not seen?

A. Certainly it included.

Q. And that were germane?

A. Certainly. That was an event that unfolded that was germane.

Q. Based upon what you had come to learn by July 8, 1986, what were the germane facts missing from your testimony on March 6?

A. I've answered that several times, but I'll answer it again. I said the draft documents from the three FDA contracts.

Q. Now, wait a minute, March 6, the germane facts missing from your testimony on March 6?

A. Right. I said were the fact that FDA already had those drafts——

Q. By March 6?

A. Yes, they did.

Q. Are you sure they had those draft survey reports from the States by March 6?

A. They had at least one of them.

Q. They had at least one, but only one.

A. All right.

Q. They had the one. Which one was that?

A. I don't remember.

Q. Are you certain that they had one by March 6?

A. Well, I have subsequently seen one that was dated January 29.

Q. And which one was that?

A. I don't remember which of the three States it was.

Q. The reason why I ask you that is because the District of Columbia report was the very first one to be given to FDA. And that's dated May 1986.

A. That was the first one that I saw. But subsequently when FDA provided you with a list of documents and provided me with the same—with copies of what they provided to the committee staff, I found in there a draft report that was dated January 29 from one of those contracts.

Q. From one of those—was it the report?

A. It was a draft report.

Q. But you didn't see it until—so on March 6 you didn't know that any of these existed; did you?

A. No.

Q. You couldn't?

A. That's right.

Q. I will now refer you to page 3 of your July 8 memo, to the first two sentences of the second to last paragraph which reads as follows, quote:

> After the hearing, Dr. Macdonald directed me to carry out an assessment of dialyzer reuse. In the course of carrying out that assessment, it has become evident the communication within the Public Health Service is less than adequate.

Now, if you would be specific now and tell us what during the course of carrying out the assessment made it evident to you that communications within the Public Health Service were less than adequate?

A. How many times are you going to ask me the same questions? Have you gotten your question sheets mixed up there? I mean we have been over this at least three times now.

Q. I don't think we have, Dr. Marshall. I'm asking you to be specific.

The WITNESS. I'd like to take a recess to confer with my Counsel.

Mr. MICHIE. Please do.

[Short recess.]

Mr. MICHIE. Let's go back on the record.

Would you please read the question before we went for a recess.

[The record was read.]

The WITNESS. OK. And the answer was that material came to light that I felt should have been shared with me earlier and hadn't been.

By Mr. MICHIE.

Q. What was that specifically?

A. We've identified primarily the—at least one draft report that FDA had already seen from three contracts even though they had told me that those contracts had not been completed for several months when in fact they already had at least one draft report in hand.

Q. Anything else?

A. No. That's all.

Q. Continuing with that same paragraph in your July 8 memo, you go on to state:

> We uncovered serious omissions and inaccuracies in the testimony which had been prepared based on facts made available last March. Some of these only came to light the day before the public comment period for the assessment expired when we

received several hundred pages of information from Senator Heinz. Included in that were internal PHS documents that had not previously been shared with us.

I inserted the word "public."

On the strength of that I requested an extension to July 10 to conclude the report. However, recent outbreaks of bacteremia and information that had unfolded from that process suggests that a report at this point might not be appropriate.

You use the word "we" in stating that serious omissions and inaccuracies had been discovered. Who besides yourself was involved in that?

A. Well, I was not involved in it. It was purely Erlichman and Carter.

Q. And were these serious omissions and inaccuracies contained in your testimony submitted from the hearing record and in your oral testimony including your response to questions, or both?

A. I think that they were primarily in my oral responses to questions. I don't believe that there were any of that in my actual testimony.

Q. Can you recall——

A. But I think I would have—Well, I think that basically I had the impression that there was a better concordance among dialysis facilities with respect to what were proper reprocessing procedures. And what I came to believe as a result of the briefings that I received from Dr. Carter was there really was more variance out there, and perhaps more vigorous and aggressive prospective standard setting would be appropriate. And I think that's the particular issue.

Q. Wouldn't that also—wouldn't that also reflect in your prepared statement, reflect on this particular sentence in your prepared statement, "Mr. Chairman, and"——

A. Could you tell me——

Q. Page 66. I'm sorry, page 66 of the record. It states:

Mr. Chairman, we consider that ample experience exists today to suggest that no health hazards for dialyzer reused been demonstrated.

If you had it to write over again, would you qualify——

A. I think if I were writing that now I would qualify it by saying that if proper reprocessing had been followed, no hazard. I think it would have emphasized that. It was implicit in that statement.

I certainly was not making a statement nor did I believe nor did the information that I had available to me suggest that it was not hazardous no matter how you did it. But probably I would have insisted on putting it in there, you know, I would have emphasized it more than we had.

And in fact, you can see that if you read the following statement I went on and said:

With the development of revised standards for the reuse and these guidelines adequate safeguards would exist.

So even there I was saying it was clear we needed to do more.

Q. And were you not referring to the AAMI recommended practice when you spoke of that?

A. Yes.

Q. Were you aware at that time that the recommended AAMI practice was still in draft form?

A. Yes.

Q. Were you also aware at that time that there was substantial controversy surrounding the draft AAMI recommended practice within the dialysis community?

A. Well, I would not accede that there was then or that there is now. Because it has never been represented to me that there is disagreement that you would characterize as substantial. My impression then as it is now is that it's been cumbersome, it has taken a long time, but it's not because there's a cat and dog fight going on, it's simply the inertia of moving people in a voluntary effort that all are busy. And there's a usual clearance before an organization like that delivers a policy, and it's bureaucratic inertia being overcome in that organization rather than somebody who takes serious issue with this.

Q. Were you aware at that time that the AAMI recommended practice did not address the reprocessing of blood lines, transducer filters, and dialyzer caps but only attempted to address the repressing of the dialyzer? Were you aware of that at that time?

A. I did not understand that at that time.

Q. You did not?

A. Right.

Q. So if you had that understanding at that time, would you have further wanted to qualify your statement?

A. Yes.

Q. You would?

A. Yes.

Q. What would you have said?

A. I would have said but these guidelines obviously have to involve looking at the entire apparatus and not just the dialyzer.

Q. And would that have indicated to you at that time during your testimony that perhaps there was indeed reason for more concern regarding process and procedure in these dialysis clinics across the country with regard to reprocessing and reuse?

A. It would have suggested to me the need for the development of standards for those. It would not have necessarily suggested to me that there was any kind of negligence out there or that there were major problems.

Q. Were you—I'm sorry.

A. It simply would have indicated the need to have these addressed.

Q. Were you aware at the time of your testimony that a goodly number of clinics were indeed reprocessing these other items, these disposable items? Were you aware of that at that time?

A. I think that I was. I recall a discussion where that issue came up. And I believe I was aware that they were using the entire apparatus—I know I was. It was raised in the hearing. And I was not surprised at all at that point in time.

Q. And I believe also in your testimony, in your prepared testimony, you spoke of CDC's annual survey; did you not?

A. Uh-huh.

Q. And you relied upon that in order to state that there had been no changes in mortality?

A. That's right.

Q. Is that correct?

A. Yeah.

Q. In light of the fact—let me ask you first: Were you aware at that time that this survey, this annual survey conducted jointly with HCFA, had never been assessed or validated? Were you aware of that?

A. Well, I was not aware of that. But I don't know that that would have made a difference. What does that mean, that it was not assessed or validated?

Q. That it had never been tested as to its validity. I mean that's pretty cut and dried, isn't it, Dr. Marshall?

A. No; that isn't cut and dried.

Q. It isn't——

A. No. There are levels at which things may be validated. And whether they are validated to the point where you publish the description of that process in a peer review journal is one standard that we hold to. When you validate that in terms of some crude assessments is something quite different.

Now, certainly had I had the Solomon and Murphy memo in hand prior to that March 6 hearing, which I could not have had because it was not written until much later, I would have said to them what do you mean by that? And I would have tried to establish to my own standard and own understanding of the constructs of validity what that means. And that's an area where I am competent technically in my own right to make those judgments because I have been a professor at the graduate level of experimental design in statistics and measurement.

So my understanding of validity and what predicative validity is and validity you use in a scientific publication, they're quite different concepts.

Q. Getting back to the CDC, don't you assume that in light of this memo and in light of what's stated in your own assessment report, that CDC knew back in March of this year that its data base had never been assessed and had never been attested?

A. I——

Q. Don't you imagine they knew that?

A. I believe they knew they had a certain level of confidence in it.

Q. Don't you think that at that time they knew that that particular data base had never been assessed or validated? Is that a reasonable assumption?

A. No; that's not a reasonable assumption.

Q. It's not?

A. I think they believed that it had been validated at a level that was consistent with the requirements of specificity for the answers they gave in that testimony.

Q. Did they know that?

A. They cleared the testimony. They didn't tell me that because I didn't discuss it with them.

Q. As a matter of fact, they sent you some briefing material; didn't they?

A. Yes.

Q. And did that briefing material discuss this data base?

A. It said that their surveillance had not uncovered serious problems with this. They had not uncovered a change in the rate. They specifically said their surveillance and that a particular study based on that surveillance showed that there was no greater incidence of hepatitis B in facilities that reused versus than those that did not.

Q. Do you recall whether that briefing material informed you that because—and I'm reading from page 28 of your own assessment report, "that because CDC has not included in their surveillance activity any specific questions dealing with increased rates of bacteremia associated with the reuse of hemodialyzers there is no data covering this potential hazard on a national basis;" did they inform you of that?

A. If they did, I certainly did not include it in my statement.

Q. Why not? If you had known about it would you not have qualified your statement to point that out?

A. I have pointed out to you that the assessment report is a much more detailed scientific document. It's many more pages than the testimony. We were trying to keep the testimony down to a reasonable size so I wouldn't sit there reading an opening statement for the entire time that the committee had set aside.

Q. Didn't you point out earlier that the reference on page 26 to the fact that this study had not been tested came from a paper in 1982; didn't you state that earlier?

A. Yes, yes. I said that that was a quote from that paper.

Q. And at that time didn't you suggest that maybe things had changed?

A. I don't understand what you're——

Q. What I mean by that is didn't you allude to this 1982 reference as something that was old?

A. I alluded to that in our discussion in what was on page 28. When you were suggesting in that statement in 1981 was something, A, my staff had said; and B, this is what the current situation was. And I was saying I wasn't willing to make that assumption.

Q. They correctly attribute it to CDC.

A. I know that. But I wanted to make sure that the record of this interview said that.

Q. Had you known these two particular pieces of information at the time you prepared your testimony, would you not have qualified your testimony?

A. That's like asking me if I were a horse and I was lost where would I be? I don't know what I would have done. My presumption is I would have, if I had read something that said this did not look at bacteremia—now but on the other hand, would I have—when you say hepatitis, that's what you mean. I didn't say it shows there are absolutely no problems. I didn't say that it led to psoriasis and the heartbreak of seborrhea either, but it doesn't.

Q. I would only point out and ask if CDC did not include these qualifiers in their briefing material to you, there's no way for you to know; is that correct?

A. That's correct. But I don't know whether they included them or whether they didn't. I don't know whether the process was one—and I think the point you're trying to make is we deliberately ignored adverse information. I think the process was one with there was a lot of information presented that got boiled down to an opening statement at a hearing. And what the reasons was why anything was in there or not in there, I can't speak to that right now.

Q. What we're going to do is try to retrieve the briefing material that you received from CDC so that you can look at it and satisfy yourself as to whether or not——

A. Well, that's really a waste of time. Because I can't set here now—even if I look at it now, I don't know whether I saw that last March 5 or whether I didn't see that last March 5.

Q. But you were just talking about what they told you in the briefing material.

A. No.

Mr. RISEBERG. I also think——

The WITNESS. I was talking about what might have been there.

Mr. RISEBERG. I would also say that this is a deposition based upon what Dr. Marshall knows and remembers as of this time. And we're not going to spend a lot of time here watching Dr. Marshall go through documents that it is not germane for him to review.

If you have questions to ask him based on what he remembers now, then ask those questions.

Mr. MICHIE. I'm doing just that, Mr. Riseberg.

The WITNESS. Well, I am not going to look at something now that you tell me I saw last March.

Mr. MICHIE. I'm not suggesting you saw it. I want to show you something to refresh your memory because the cover sheet of that material is addressed to you. It's just as simple as that.

Do you have objection to looking at that?

The WITNESS. I get 100 pieces of paper addressed to me.

Mr. RISEBERG. He's prepared to answer on his present recollection and there is no need to refresh his recollection in any way for this deposition.

By Mr. MICHIE.

Q. In the meantime let's go on with the questions.

A. Let us.

Q. Do you recall which of these admissions and inaccuracies as you state in the July 8 memo only came to light after you had received several hundred pages of information from——

A. I refer you to my previous responses to that. I have recalled as many of those as I can.

Q. Now, this has to do though with Senator Heinz's material that was sent to you.

A. Right.

Q. And what was——

A. I did not personally review the material that Senator Heinz sent to me.

Q. I understand. So if you didn't review it personally, then you don't know?

A. I say I don't know.

Q. Regarding the last sentence of the second to the last paragraph, you refer to additional information that had unfolded from the recent outbreaks of bacteremia infection. Would you identify and elaborate on that additional information.

A. Yes; I think that that had to do with something that is of very great concern to me at this point that we have not yet touched on in this protracted discussion, and that is that I am much more concerned about the effects on reprocessing of the fact that facilities are switching to other kinds of disinfectants out of concern for the potential effects of formaldehyde, not on the dialysis patient but on the staff that's doing the reprocessing.

I am much more concerned about that than I am about the rate question. And that is essentially what I was talking about in that sentence. Because what I see is a situation where people will start using these alternative disinfectants out of concern for their staff, and as a result of complaints and concerns from their staff, and that this will not do an adequate job of disinfecting.

And that's really what is represented in that sentence. I was saying that until the FDA completes its investigation, until we decide about Renalin and ReNew-D and other kinds of things, then I think this is something we need to be worried about. And we need to be on top of making a set of recommendations about what are the proper disinfectant procedures. And that's really what I was referring to in that particular phrase of that sentence.

Q. Procedures with regard to inadequate procedure, with regard to there being no procedures in writing, with regard to the process not being followed, is that what you're——

A. No, no. I'm talking about—I believe that there are procedures involving the use of formaldehyde that are pretty much state-of-the-art, and that most places that are reprocessing with formaldehyde are doing it that way.

But I'm concerned as people switch to other kinds of disinfectants that unless we take some careful steps to decide what works, at what concentration, for how long, there could be some potential for some increased risk, exposure hazard, as a result of this switch to other kinds of disinfectants. And that is that that's driven by the CDC report for instance on the use of formaldehyde and the vaporization of formaldehyde in the reprocessing settings.

Q. Are does that mean that you are not aware that the reports, the materials, that CDC developed following and during the five investigations of the five clinics, are you saying tht you're not aware of their findings in that there were serious problems found regardless of what chemical was used in following procedure, in following protocol, and in one case in not even having the procedure in writing? Are you aware of that?

A. Well, I am aware of that.

Q. Doesn't that concern you?

A. Yes; it concerns me. And that's why I made recommendations to the Assistant Secretary for Health with respect to the need for CDC and FDA to do something about that.

Q. To do what?

A. To develop some standards, to develop some tests, to work together to come up with a set of clinically and scientifically sound procedures.

Q. He's going to enforce that?

A. I—that's not the question. You want me to answer that question? I can tell you who would enforce those.

Q. Who would enforce these standards?

A. I think there are several ways how we enforce those standards. I think what we rely on—as we all do, we rely on ethical behavior of physicians who treat patients. And as a secondary process, backup, we communicate that to HCFA so that they can put that in instructions to their State contractors who do the survey.

I tell you as certain as we are all sitting here there is absolutely no way, unless you put an FBI agent or investigator from this committee staff in every dialysis center 24 hours a day, that you can comply with that. You have—the ultimate reliance there——

Q. What about FDA inspections? What would be wrong with that, Dr. Marshall?

A. I don't think that that would add a whole lot to it.

Q. You don't?

A. FDA inspects tunafish and vichyssiuse and ice cream bars, and sometimes you have something bad happen there unless the inspector is there every hour of the operation. The question is what's the incremental value? What's the incremental value? I don't know. What I'm saying to you is ethical medical practice is what it relies on.

Q. The only data base we have to rely upon is the findings of the CDC and five investigations that they conducted—incidentally at the pleasure of the States and clinics because they can't go in without invitation?

A. Right, unless they're invited.

Q. The results of those studies as well as the results of the surveys, especially those by the District of Columbia and by California, would that not indicate to you—because after all in all five investigations conducted at all five clinics, my recollection is that inadequate procedures and so on were found in every instance?

A. It has—it does suggest that to me. And I have recognized that. And in the recommendation that we have made and in the course of action that we have recommended for the PHS agencies I have said develop those and transmit those to the Health Care Financing Administration.

Now I am not the Health Care Financing Administration.

Q. I understand.

A. And when they ask me how they should do that, I will give them an answer to how they should do it. And it will be thoughtful and deliberate as all my answers are.

Q. I will show you now a facsimile cover sheet, you are listed as the addressee. It's dated March 4, 1986. And it's from a Ms. Depister, Francis Depister. Do you recall receiving that?

A. No; but I don't recall not receiving it either, Mr. Michie.

Q. Fine. You will note here that there is a one-page summary of CDC surveillance system; is that correct?

A. Uh-huh.

Q. Now, do you find anywhere in that summary anything at all referring to the fact that that surveillance system has never been tested or assessed for validity purposes?

A. No; I do not.

Q. Do you find anywhere in there where it states that because CDC has not included in their surveillance activity any specific questions dealing with increased rates of bacteremia associated with the reuse of hemodialyzers there is no data pertaining to this on a national basis? Do you find that in there?

A. No; I don't find that in there.

Q. Why do you think it's not included? Do you have any idea?

A. No.

Q. Do you think it should have been? Do you think it would have been informative to you in preparation of your testimony?

A. I think it would have been informative to me. But they had to make a decision how much information they were going to provide. They had a timeframe.

Q. Of course you're not responsible for their judgments. But what I'm asking you is don't you think those are pertinent things that you should have been made aware of prior to your testimony?

A. Well, if in fact they had evidence that showed that their data base was weak, inappropriate, or unsatisfactory, they shouldn't have even referred me to it. The fact that they did refer me to it tells me that they must have some level of confidence in it.

Now, the level of confidence that they have in it was such that they clearly had done this particular study. I don't know whether that meant they didn't do a study of bacteremia or whether they didn't they have the capability to do a study for bacteremia.

One of the things that is a problem with dealing with scientists, certainly that I have with my scientists and I know that Dr. Mason occasionally has it with his scientists, is when you're trying to translate science into public policy the natural inclination of scientists is to say here's why this works but here are nine reasons maybe you ought to be skeptical about the answer I'm giving you.

That's all right in scientific journals but that doesn't help you. Because it shows you're careful and cautious and therefore a good scientist. That doesn't help you when you're trying to create public policy. It was Harry Truman who said give me a one handed scientist who doesn't say on the other hand when that——

Q. Dr. Marshall, you used the statistics, some of them, from that particular summary there in your testimony?

A. Yes.

Q. To buttress your statement that there were no serious problems with reuse; didn't you?

A. Right, yes.

Q. Do you think you could have made those statements had they included these facts and these qualifiers? Would you have made that same statement?

A. Do you agree that hepatitis B is a serious complication? That's all I said. It's hepatitis B. Then I used that to buttress other kinds of things. But that was only one of many inferences that I made as to why it was safe.

Would I have said something different had he said yes, but his system is completely unvalidated? If they said that, I probably wouldn't have used it.

Q. Fine.

A. If they had said but remember don't apply this beyond hepatitis, I would not. But they didn't say that and I'm not sure they should have said that.

Q. At the very bottom of page 3 of your July 8 memo is a paragraph with the heading "Action," and reads as follows:

> The PHS needs to take a clinically and scientifically based stand with respect to this issue. We need to communicate that directly and emphatically to the Health Care Financing Administration even if that means recognizing that our earlier testimony was flawed.

A. Uh-huh.

Q. Now, in this July 8 memo of yours, Dr. Marshall—and we've gone over much of it and read a lot of quotes from it—were you not in effect trying to get a message across to Dr. Windom, that message being in light of the recent infection outbreaks in clinics and new information that Senator Heinz and his committee staff had continued to provide to you and your staff, weren't you trying to warn Dr. Windom that the original plan to perform a rush job type of assessment to accommodate HCFA probably was not going to work?

A. No. That's a total—it's a very clever but inappropriate condensation of various inferences and events.

Q. The answer yes or no suffices.

A. No, the answer yes or no does not suffice to that kind of question. That's like when did I last beat my wife.

Q. Please elaborate on your answer if you wish.

A. I will elaborate on my answer. What I was saying is even at that writing there existed uncertainty with respect to what our policy should be. And there certainly was not adequate data on which to base a policy. That what it was going to be necessary to do was to carry out some studies which I had previously said we didn't do.

I had previously thought that we perhaps had as many answers as we needed. But I decided—and this is clear in the assessment and in the recommendations that accompanied it, and in the——

Q. Wait a minute now. I thought the recommendations were separate.

A. They were. But that accompanied it to Dr. Windom. The assessment and findings and conclusions are one piece of paper. The recommendations are another——

Q. Two separate documents; is that not correct?

A. Absolutely, two separate documents.

Q. Please continue.

A. But they were transmitted to Dr. Windom as different attachments to this same memorandum.

Q. Were the recommendations sent forward to Dr. Roper?

A. I can't answer that. I don't know whether they were or were not. I did not send anything forward to Dr. Roper.

Q. Did you want to add anything to your answer?

A. Yes, I do. I want to add to my answer.

Q. Go right ahead.

A. So what I was saying to him was not that our earlier testimony was flawed, but I was saying that we may come up with findings and we may come up with recommendations that would give rise to that as a reasonable inference. But what I was saying to him was that we needed to do some studies, that we needed to determine what was the point at which a filter might be compromised as a result of reprocessing, that we needed to determine whether the point at which a filter was compromised, was that different from the point at which the tubing or the filter caps or the transducer might be compromised as a result of reprocessing?

Because I don't know and nobody knows whether that's the same point. Maybe you can use a filter 100 times and you can use the tubing 200 times. Maybe you shouldn't use any of them more than 10 times.

Q. Maybe you shouldn't use them at all; is that right? Maybe you shouldn't use them at all?

A. I would say maybe. But I would say that's a slender maybe.

Q. But still the possibility is there?

A. I would say the fact that they've been reused since 1963 and reuse is increasing——

Q. Is that correct?

A. [Continuing.] With every passing day and every passing week, it reduces the possibility that your hypothesis is correct, that they should not be reused. But I testified on March 6 you recall in direct response to one of the Senator's questions, when he asked me whether I thought that 50 was too many, I said that intuitively I thought that was probably beyond the parameters of acceptability but that I didn't know and I thought we needed to find out.

Q. What number would you chose?

A. I wouldn't. I have no knowledge.

Q. But reuse is going on right now. What advice would you give as director of NCHSR to a clinician? What advice would you give to him now as to the number of uses?

A. I wouldn't.

Q. You wouldn't?

A. Right.

Q. What would you tell him?

A. I would tell him he would need to monitor his patients clinically for times that there was toxemic buildup.

Q. Even if he reused 40 and 50 times?

A. Yeah.

Q. That's all right with you?

A. I don't want this to be construed as I'm saying 50 is all right. I'm saying we didn't know. And the proof of the pudding is does it work? It's conceivable to me that a filter might not be any good after two reuses. There are some that aren't any good the first time.

I presume the quality control in manufacturing these the first time isn't literally perfect. But I'm saying that the judgment is one that a clinician has to make. I don't think we can say after this many times or after that many times. What we say in our recommendation is that somebody needs to develop a test as to what the clearance and characteristics of a filter after it's been reprocessed.

Q. We don't even know that?

A. That's what I said, we don't know that and need to establish studies to know that.

Q. So what advice would you give to the clinicis?

Mr. RISEBERG. He's already answered that question.

The WITNESS. I said I would monitor patients carefully, which you should do anyway, and if you see—you are seeing any clinical signs of toxemia, you see what you have to do. Maybe what you do is pop a new filter into the line. Maybe what you do is adjust the medication.

And we've had discussions about that during the hearing. Some people just give them more Heparin. That's not a judgment I'm about to make. Because the minute I make that I'm wrong because I don't know.

By Mr. MICHIE.

Q. Are you aware that in it's investigation of these five clinics that the CDC determined that in at least two and possibly three of these clinics that there was a statistically significant correlation between the number of reuses and the number of patients suffering from infection, in other words, the more reuses of the dialyzer the more likely the patient would suffer infection? Are you aware of that?

A. I have not been—no one has brought that particular study to my attention. It may have been brought to Dr. Carter's, but certainly not to mine.

Q. That particular result is reposited in your files over at your office, and it's been there since August 11.

A. Well——

Q. I think you'll find it there.

A. I didn't—you know.

Q. You weren't aware of that until right now? Does that give you pause for thought——

A. No.

Q. [Continuing.] About what you just stated about the number of reuses?

A. No.

Q. Not at all?

A. No. Because unless I knew what the numbers were—unless I looked at what those mathematical functions were, unless I looked at what statistical test they applied, that may or may not give me pause. If I go and look at that data myself, which is what scientists and clinicians do, I would be prepared to make that statement.

Q. Do you intend to do that?

A. Huh?

Q. Do you intend to do that? Do you think it's important enough for you to take an interest in this?

A. I think I'll ask Dr. Carter about it. And I may take the numbers home and run it in my own statistical program, if I have time.

Q. Do you intend to consult with CDC about these findings?

A. No.

Q. You're not interested in discussing these with him?

A. I'm not in the context of this. Because I think it will be addressed and discussed with any recommendations and procedures that they pursue, I think that's something that will certainly be addressed by the task force that Dr. Windom has established. And I will see to it that Dr. Carter raises that in those discussions. But will I personally followup on it? No.

Q. Had you known about this particular result that was calculated after visits to these five clinics, had your staff known about this, had you known about it prior to August 6, do you think that would have been important enough to include in that assessment?

A. We would have made reference to it, certainly. Whether it would have changed the outcome, I don't know. Because that kind of correlation could be there's a correlation, you've only started seeing this after you've used them 100 times, you know, to 150 times.

Q. Of course there's no way for you to know that now?

A. There isn't. That's why I wouldn't go beyond saying we would have discussed that having that finding——

Q. And my response is how could you know because you didn't have the material; isn't that right?

A. Right, that's correct. I did not have the material. But even if I gave full scientific credence to that finding, it would not have influenced either our conclusions, nor would it have influenced the recommendations that I made.

Q. How can you state that when you haven't looked at the material?

A. I can state that because we're talking about 1,300 dialysis facilities, we're talking about 72,000 patients, and we're talking about statistical probabilities and about what the impact of this is. And I have already made recommendations that say that we need to carry out these studies and we need to develop some standards. There's nothing more than I can do about it.

Q. Nevertheless, you did state a little earlier you would have found it important enough to reference in your assessment?

A. Surely. But I didn't want to leave an impression that that single piece of information would have caused a major reversal of either the findings or recommendations.

Mr. RISEBERG. But, of course, you haven't seen the studies?

The WITNESS. I haven't seen the studies.

Mr. MICHIE. That's understood. We haven't gone through that.

By Mr. MICHIE.

Q. During the July 8, 1986, meeting at which you presented your memo of that same date concerning hemodialyzer reuse with others in attendance, was there discussion of that memo?

A. No. We just walked through those points.

Q. There was discussion of the memo; was there not?

A. No, there wasn't discussion in that somebody from FDA says that's a crock or you got your facts wrong. I simply used that as a text for briefing Dr. Windom.

Q. Were copies of this memo given to all participants in the meeting, all attendees?

A. I think there were more people there than there were copies.

Q. Did Dr. Windom get a copy?

A. No.

Q. He didn't?

A. Well, he had one in front of him during the meeting.

Q. Then he received a copy?

A. But, no, I took it from him when the meeting was over.

Q. I understand that.

My question was——

A. Was there a memo at his place, yes. Did he read it there, no.

Q. I did ask you that question.

A. But I answered that question. Because the way you asked the question, my answer was it could be construed——

Q. We will get to that in a moment. Give me a chance now, Dr. Marshall. We have to ask these questions one at a time.

A. We certainly do.

Q. So I would appreciate it if you wouldn't anticipate what I would ask next.

A. I would appreciate it if you would ask them one at a time.

Q. During the course of that meeting, did someone admonish, criticize, or perhaps even scold you for having written that memo in the first place?

A. No.

Q. Did anyone not make any comment to you about your memo?

A. Did anyone not make any comment?

Q. Did anyone at all make comments to you——

A. Let me save you some time.

There was a comment made by Steven Grossman.

Q. Who is he?

A. Steven Grossman is the Deputy Assistant Secretary for Health Planning and Evaluation.

Q. What did he tell you?

A. He said, well, this is pretty frank, or words to that effect, you weren't planning to distribute this, were you? And I said no, I am planning to collect all the copies when the meeting is over.

Q. Did he not ask you to retrieve all of the copies?

A. Well, I think that was implicit in that discussion. I have not quoted word for word what happened, because I don't recall.

I had talked about what the sense of it was. He clearly agreed with my suggestion that it would be a good idea to collect the copies.

Q. Is he the person who suggested to you that you retrieve all of the copies and dispose of them? Did he tell you that?

A. No, not to my recollection.

Q. You don't recall him saying——

A. There was this exchange between Steve Grossman and myself, and I volunteered to do that. And he said that is good, or words to that effect, or maybe he said you should—I hope that's what you're going to do. And I said sure. I didn't work for him. He doesn't admonish me or give me directions.

Q. Do you remember him advising you to get rid of that memo?

A. No.

Q. You don't?

A. No. And I don't think he would have done that. I think—and I say that based on the collegial relationship that exists between us. And I think it's pretty well known in the Public Health Service that I am not somebody that takes that kind of direction well.

Q. Getting back to an earlier time, do you recall my having telephoned you on June 9 to inform you that Senator Heinz would be submitting comments and a response to your Federal Register notice of April 10? Do you remember that?

A. Yes.

Q. Do you also recall my having asked——

A. Go ahead. I am sorry.

Q. Go ahead, please.

A. You told me they were on the way, that Mr. Cunningham was on the way.

Q. Correct. Correct.

Do you recall my having asked you during that same conversation whether or not you were aware of recent infection outbreaks in dialysis clinics that practice were used? Do you recall me telling you that?

A. Yes.

Q. And do you recall having responded to me that you were not aware of those outbreaks at that time?

A. I don't remember whether I was aware of them—whether I was or was not. I think I was aware of them because I think that Dr. Carter had mentioned it to me—no, no, excuse me. I don't think that on June 9 I was aware of them.

Q. So, then, would you agree that I was probably the person who informed you in the conversation we had?

A. Well, my recollection of that conversation is that I wasn't certain whether you were just talking about that again, or whether you were talking about something new.

Q. But you found out soon after that though that what I had told you was in fact the truth, isn't that right?

A. Oh, yes, I don't dispute that.

Q. FDA and CDC internal documents indicate that these infection outbreaks were discovered beginning in early April perhaps even late March. Is that your understanding?

A. That's my understanding, yes.

Q. When did you come to learn that?

A. I don't recall.

Q. Well, it must have been——

A. It was probably shortly after your phone call, and I probably called Enrique and said, you know, does Michie know something here or——

Q. Can you recall——

A. [Continuing.] And he knew—when I told him about what you told me, he knew about it.

Q. Can you recall approximately when you were informed by FDA or CDC about these infection outbreaks? When did they let you know?

A. Well, I wasn't dealing with FDA and CDC then so I can't really answer that question. They were dealing with Dr. Carter, not with me.

Q. But I mean on—what I am getting at is we have a June 25, 1986, memo addressed to you from Mr. Benson, James Benson, Deputy Director.

A. Probably.

Q. And we will show that memo to you.

And to your recollection, was this the first notification from FDA to you about this whole situation?

A. I don't know. It certainly was the first written one. But I don't—again I didn't personally, start receiving a great deal of material from FDA until after my confidential memo to Commissioner Young, at which point he told his staff give them everything. So then I started getting everything. I read very little of it. Mostly when it came in, I put EC on it and went down to Dr. Carter.

Q. Did there come a time during the conduct of the assessment when Dr. Carter complained to you about the lack of cooperation and response from FDA, CDC, or NIH in providing OHTA——

A. Dr. Carter came to me on several occasions and said look at this, here is something we have turned up that we should have known about.

Q. Or here is something that the committee staff gave us or should have been given to us by those agencies?

A. Well, I don't know whether, you know, he necessarily attributed it to the committee staff or whether it was——

Q. Isn't that possible though?

A. There certainly was at least one occasion when he said well, there is a lot of stuff in there we hadn't seen before.

Q. And you are aware of the fact that we continued to send you material right along, arent' you?

A. Oh, the committee staff has been helpful, sometimes to excess.

Q. Let me share with you now, on May 28, 1986, a memo to Dr. Carter, Director of OHTA, and Dr. Robert Veiga from the Office of Health Affairs at FDA.

Do you recall having seen this memo at the time it was received by Dr. Carter? Did he share that with you?

A. No.

Q. This memo responds to Dr. Carter's request on April 9 pertaining to dialysis device reuse, and I think you referred to that particular request earlier in this deposition. Dr. Veiga's May 28 response to Dr. Carter states:

> All information concerning the information of reuse of hemodialyzers, transducers, filters, and dialyzer caps is already available to OHTA as part of the package for Senator Heinz's hearing. The office has no additional information.

Didn't you know upon reading, if you recall reading, this memo that this wasn't a true statement?

A. Well, I don't recall having read this memo at the time. But certainly if I had read it, I would have said, you know, who is he kidding?

Then, on the other hand, I also know that Dr. Veiga worked in the Office of the Associate Commissioner for Scientific Affairs. Dr. Veiga is our normal channel, or he and his supervisor and colleagues are our normal channel for FDA. We don't normally go into the bowels of FDA and deal with people directly. We generally send the written question to Dr. Nightingale and his staff, and stuff comes back from there.

If I had read that, I would have said who are you kidding? Bureaucracy strikes again. And this is Kobren and Eccleston and people from the Radiological Office bringing great gobs of paper back and forth. Somebody in their executive secretariat says we never sent a response over to NCHSR, and we should have. And Veiga whipped this thing off, but it was superfluous.

Q. Were you aware during the meeting for the June 27 edition of Morbidity and Mortality Weekly Report?

A. It was brought to my attention by Eccleston.

Q. Of FDA?

A. Yes.

Q. Did you become involved during that week in discussion with anyone at CDC about this?

A. Yes. I picked up the phone and I called CDC.

Q. And what did you ask about them, do you remember?

A. What I told them was that I—I asked them what the language was that they were going to use, was it the same as what FDA read to me, and I was suggesting to them that the language they were proposing to use was not language that I would find great favor with. And I suggested some alternative language.

Q. Do you recall what that language was in so many words that you didn't like?

A. My recollection is they said there should be clinical trials. And I explained to them the implications of clinical files were probably something beyond either what I had testified to, what NIH would agree was appropriate, or what was—this was the most important of all—what was necessary.

And I suggested they should include language which suggested the need for studies on which standards could be based. And that was pretty much the language that we agreed upon. It was not a heated discussion. It was a discussion between colleagues. And they usually acceded to what I suggested.

Now——

Q. How could you reach that conclusion during the week of June 22 when your assessment was going to run for at least another month? How could you make such a definite statement to CDC that you knew then that clinical trials were not to be conducted because they were not necessary? How could you make that?

A. I didn't care whether that was going to be our recommendation or whether that wasn't. I did not want CDC to make that recommendation while the Office of Assistant Secretary for Health had a study pending. Because if I had—I was trying to preserve our options to find what needed to be found. And I didn't want to be in the situation where we found one thing and somebody said to me here is what CDC said.

So I suggested they could accomplish their end just as—they would do what they needed to do and meet this responsibility. And I was clear to them that if they really felt that you needed clinical trials, that that is what they should. But they agreed that, you know, to what we all looked on as an editorial change, we say you needed studies. They could be clinical studies or could not be clinical studies, prospective, or they could be retrospective. But I asked them not to undercut what we were doing.

Mr. Michie. Let's take a 2-minute recess at this time. We are almost done.

[Short recess.]

By Mr. Michie.

Q. I would like to share with you drafts of that article. And these other drafts that were provided to you by CDC. They are drafts 1, 2, 3, 4, and the final version, the version that was published.

I would like for you to quickly scan them—I don't think you need to read the whole entire article. I think that what you are referring to would have appeared in the editorial note.

A. That's correct.

Q. So would you just scan those and see if you see anywhere in those four drafts anything at all that recommends clinical study?

Mr. Riseberg. Are they chronological in order here?

Mr. Michie. Yes, they are.

The Witness. Well, I didn't—I never say these drafts.

By Mr. Michie.

Q. You never say any of them?

A. Never say any of them. I was responding only to what I was told over the telephone by Eccleston.

Q. Do you recall the date of that telephone conversation?

A. No.

Q. You don't?

A. No.

Q. It wouldn't have been——

A. It was—it was on Tuesday or Wednesday for the Friday MMWR.

Q. Tuesday or Wednesday?

A. Yes, probably—no, let me retract that, I don't know when it was. It was several days before. There was time for them to make changes in it.

Q. Could it have been the 23d or 24th, do you think?

A. It could have been.

Q. Now, if you turn the page there and look at draft No. 1, you find that is in the editorial page—and it's on page 3 of that draft, there's a mention of there—there is a statement in there about there not having been clinical trials. Do you see it there?

A. It's up above. There are no controlled clinical studies validating the safety or assessing the risk, yes.

Q. What else does it say there?

A. Nor are there controlled clinical studies with new dialyzers without patients being dialyzed with reprocessed single use dialyzer "morbidity or mortality studies."

Q. Is that what the FDA could have been concerned with do you think? Because you will note that the particular passage was dropped after the first draft, it doesn't appear in drafts 2, 3, 4.

A. I am not willing to speculate on that. I don't know. I had no discussion with FDA, what they liked or didn't like.

Q. The reason I asked——

A. They called to alert me to an issue. They called me to remind me that there was no reference in here to however the Public Health Service is doing an assessment of these issues. And they didn't ask me to do anything or not do anything. They just asked me had I had any discussions? And I took that in part of them trying to find out whether that was something I was working on with CDC.

Q. You know, I asked that question in this context, since that's the only reference to controlled clinical studies anywhere in any of those drafts. And since you didn't see any of the drafts, but you received a call from FRA would you say it is possible that that is the passage that concerned FDA? That is what my question is, just your mention of controlled studies?

A. Of course, I would have to say it is possible because it would be absurd to say it wasn't possible.

Q. Do you have any knowledge at all what changes were made in the article as per the request of FDA? Do you have any knowlege?

A. No, no. I didn't discuss that with them.

Q. Now, I would like to share with you your July 25 confidential memo note that you sent to FDA, Commissioner Young.

A. Yes.

Q. And I think you stated earlier that along with this you had provided him with an inventory of documents that you felt should have been shared earlier with NCHSR, but had not been, isn't that correct?

A. No, that's not. I mean there was a list with them, but I did not characterize them as documents that should have been shared. He asked me whether I could give him a list of what we didn't—what we had not received from them, but had subsequently received. And I gave them a list that showed what they were. And I may—it's certainly in the conversations, and I will have to read—all right, I said it in the memo. I said a list of documents currently in our files is attacked as we discussed, the items marked in yellow are those which have only recently been brought to our attention, not all of them involved FDA, and clearly not all are significant, but some are, and they should have been shared earlier.

More important, our other documents which still not have been discussed with us, chief among these are trends or preliminary results from the several State survey contracts.

Q. Now, in the second paragraph of your memo, you state:

> The question is whether we are doing enough to continue to protect patients as dialyzer reuse becomes more frequent, as dialysis centers attempt to cut costs, and as more centers reprocess with disinfectants other than formaldehyde in response to the concerns of patients and staff.

Looking at all of these things that you state in here, continuing to protect patients as reuse becomes more frequent, as dialysis centers attempt to cut costs, as more centers reprocess with other disinfectants, isn't precisely what's been going on and what is still happening in response to HCFA's reduction of the reimbursement rates?

A. It is something that has happened and will happen, continue to happen, for a variety of reasons, including the level at which the Health Care Financing Administration reimburses. But I would not attribute that as the only cause.

Q. Based upon your knowledge to date, Dr. Marshall, as Director of the NCHSR, and having taken much interest in its assessment, do you believe it is wise at this time to encourage in any way increased reuse in dialysis clinics? Do you believe that is wise at this time?

A. I don't think it represents a significant hazard for people to reuse.

Q. That wasn't my question.

Do you think it is wise to encourage in any way increased reuse in these dialysis clinics?

A. The position is I neither encourage or discourage it.

Q. But I didn't ask you that either.

A. But that's what I answered.

Q. This is my question again to you, Dr. Marshall.

Based upon your knowledge to date, do you believe it would be wise at this time for anyone or anything in any way to encourage increased reuse in dialysis clinics?

A. And my answer is that the evidence is such that I am not prepared to take a position saying that we should encourage it or discourage it. I certainly would not encourage it, but I certainly would not discourage it. I don't have—I don't think that I have the ability to say, hey, this is the greatest thing since canned beer, let's all go do it. I think it would be inappropriate to do it. I think it is inappropriate to say but you are already in mortal peril to do it, because neither would be true.

Q. Doesn't it stand for reason that for economic reasons the HCFA reductions on the reimbursements will probably result in an increased reuse?

Doesn't that follow?

A. As I have already said, there are a number of factors that may influence reuse. That certainly that's one of them. But it is not the only one, and I don't know whether it's the most important one.

Q. Do you think that if this is the case and if it doesn't stand to reason that these reductions and reimbursements will encourage increased reuse, do you think that that is good for the patient?

A. I don't know whether it's good or bad for an individual patient. I think that depends on the circumstances. I think if they are reprocessed using the appropriate mechanisms, if we can say here's a test that shows that this filter is working fine, that its volume and clearance characteristics are within an acceptable range even though its been reprocessed *x* number of times, then I think it is perfectly acceptable clinical behavior.

Q. But here again——

A. And I am particularly distraught about that, knowing what I know about the first-use syndrome. And that gets to the heart of this draft statement that we looked at——

Q. Really?

A. That we really don't know enough whether the risks are greater having a new one every time than having a reused one.

Q. In your statement now you used several "ifs"?

A. We have used a lot of those "ifs."

A. As a matter of fact, right now you really don't know what's happening in those clinics? The only evidence that you have at the present time to tell you what is happening out there is what has been reported voluntarily to CDC and FCA?

A. No; that is incorrect.

Q. Isn't that right? In addition to the surveys that were conducted by these States and the District of Columbia now—let me finish.

What I am saying is that is the only evidence you have with regard to what is happening out there in procedure and process; is that not correct?

A. That's now correct.

Q. Tell us what is?

A. Because what is as important in making this judgment is what we don't have. And what we don't have is evidence that there are major outbreaks of bacteremia. What we don't have is evidence that there are major patient complications for premature morbidity.

Q. Isn't that because it hasn't been reported?

A. I don't know if it is because it hasn't been reported or whether it is because it has not occurred.

But, based upon my knowledge of what happens in medicine and health care, I am very, very comfortable in saying because it is not occurring and not a situation of occurring and not being reported.

When you look at how long patients live on dialysis, when you look at the cause of death, you don't see bacteremia as a major cause of death in patients——

Q. Dr. Marshall——

A. [Continuing.] And I don't see any difference in bacteremia with patients dialyzed with reused filters.

Q. We have already gone over that, and we have established that your own assessment reports point out that there are no supported questions with regard to incidents of infection.

So how can you make the statement you just made?

A. Because there are other kinds of infection registers that are kept. There are causes of death records on death certificates. And I am telling you that if there were a major relationship between people who are on dialysis and their deaths from bacteremia, someone would have looked at that, and it would be reported in the literature.

Q. Isn't it the case that you would hope someone would have reported that?

A. Yes; I would hope someone would have reported that.

Q. Isn't that more accurate, because there is no way for you to know?

A. No way for me to know anything, you know.

Q. That's correct.

A. There's no way for me to know that this whole thing this afternoon is not an allegory of the cave. But I can speak with reasonable scientific certainty and with reasonable certainty based on my knowledge and experience, and the fact that I frequently and have for so many years now read medical journals that there would be a note in the New England Journal of Medicine from some bright young guy who is running a dialysis unit or any one of the other journals that our staff looks at.

There will be papers given at nephrology meetings.

Mr. MICHIE. Dr. Marshall, in recessing this deposition, I would only suggest that you go back and you read the material from CDC, and you go back and you read the State survey reports, you go back to your office tomorrow and call the CDC and talk with Dr. Murphy and Dr. Solomon to get their opinions on what they have seen and found in the field.

Now, in the meantime, we are going to recess this deposition. I want to remind you that you are subject to recall.

Thank you, gentlemen.

[Whereupon, at 5:45 p.m., the talking of the deposition was recessed.]

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

J S Marshall

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this 24th day of September, 1986, and executed the above certificate in my presence.

Jerry Ann Tipton
NOTARY PUBLIC IN AND FOR
P.G. Co. Maryland

MY COMMISSION EXPIRES: July 1, 1990

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of the General Counsel

Public Health Division
Room 4A-53 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857
(301) 443-2644

September 24, 1986

CERTIFIED MAIL - Return Receipt Requested

Mr. James Michie
Chief Investigator
Special Committee on Aging
United States Senate
Room G-33, Dirksen Building
Washington, D.C. 20510

Dear Mr. Michie:

On behalf of Dr. John E. Marshall I am returning the Transcript of Proceedings dated September 11, 1986, together with his errata sheet. The Transcript was received by Dr. Marshall on September 22, 1986.

Sincerely yours,

RJRiseberg
Richard J. Riseberg
Chief Counsel
Public Health Service

Enclosures

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

Sept. 18, 1986

Dr. John E. Marshall
2704 36th St., N.W.
Washington, D.C. 20007

Dear Dr. Marshall:

Enclosed is a copy of your deposition transcript. Pursuant to Rule 6.4 of the Special Committee on Aging Rules, you are required to review it, make any appropriate changes, and sign the certificate. Please note your corrections on the separate sheet provided. The transcript, certificate, and errata sheet must be returned to the Aging Committee office at G-33 of the Dirksen Senate Office Building within five days.

Thank you for your cooperation.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

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STEPHEN R. McCONNELL, STAFF DIRECTOR
DIANE LIFSEY, MINORITY STAFF DIRECTOR

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

August 28, 1986

Mr. Richard J. Riseberg
Chief Counsel
U.S. Public Health Service
U.S. Department of Health and
Human Services
Parklawn Building, Room 4A53
5600 Fishers Lane
Rockville, Md. 20857

Dear Mr. Riseberg:

I have reviewed transcripts of the appearance of your clients, Drs. John E. Marshall and Enrique D. Carter and Mr. Martin N. Erlichman, at depositions of the Special Committee on Aging on August 22 and August 26, 1986. I have noted your clients' refusals to take the oath that Committee Rule 6.3 provides for the court reporter/notary public to administer at the outset of a deposition.

Based on the remarks of your clients and yourself at these depositions, I understand your clients to have raised two objections. First, you have questioned the legitimacy of the Committee's issuance of subpoenas directing witnesses to be examined by Committee staff at deposition, without the presence of Members of the Committee. Second, you have questioned the authority for an oath to be administered at a Committee deposition by anyone who is not a Member of Congress.

I request that you communicate to your clients that, upon consideration of these two objections, as Chairman of the Committee, I have overruled both objections. First, section 104(c)(1) of Senate Resolution 4 explicitly authorizes the Committee to require the attendance of witnesses by subpoena and to take depositions. Your apparent contention that the deposition authority does not authorize depositions by Committee staff is incorrect. The word "deposition," in contrast to the word "hearing," refers to examination by staff only. This interpretation of the word "deposition" is the only interpretation that is consistent with well-established congressional practice as well as the common meaning of the word in extra-congressional legal contexts. I rule that the Senate has authorized the Committee to subpoena witnesses to testify at depositions conducted by Committee staff.

Second, Committee Rule 6.3, which provides for the administration of oaths at staff depositions by "an individual authorized by local law to administer oaths," is consistent

with governing legal authority. Your contention that section 104(c)(2) of Senate Resolution 4, which authorizes the Chairman or any Member of the Committee to administer oaths, precludes a notary public from administering an oath at deposition is incorrect. Section 2903(c) of title 5 of the U.S. Code, in concert with section 104(c)(1)(G) of Senate Resolution 4, pursuant to the Senate's constitutional rule-making power, authorizes administration of oaths to witnesses at Committee staff depositions by individuals authorized by local law to administer oaths. Accordingly, I rule that your clients are required to take an oath to be administered by any individual designated by the Committee staff who is authorized to administer oaths by local law.

I would appreciate your advising each of your clients who has refused to be examined by Committee staff at deposition under an oath to be administered by a notary public of my rulings on their objections. If Drs. Marshall and Carter and Mr. Erlichman remain unwilling to comply with the requirements of the subpoenas with which they have been served, subpoenas may be issued compelling their attendance at a hearing of the Committee in order for them to show cause why they should not be held in contempt of Congress. Please advise Mr. James F. Michie, Chief Investigator for the Special Committee on Aging, and Mr. Morgan Frankel of the Office of Senate Legal Counsel, of your clients' intentions.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

Enrique D. Carter MD

Enrique D. Carter, M. D.

I hereby certify that the individual representing himself/~~herself~~ to be the above-named individual, appeared before me this 29th day of September, 1986, and executed the above certificate in my presence.

Mary L. Ferry

NOTARY PUBLIC IN AND FOR

Clark County, Nevada

MY COMMISSION EXPIRES: March 28, 1987

MARY L. FERRY
Mar. 28, 1987

FRIDAY, SEPTEMBER 12, 1986

Washington, DC.

Continued deposition of Enrique D. Carter, called for examination by the Special Committee on Aging, pursuant to subpoena, in room SDG-31, Dirksen Senate Office Building, Washington, DC, beginning at 8:25 a.m., before Albert R. Sparks, a notary public in and for the District of Columbia.

Appearances:

For the Special Committee on Aging:

James F. Michie, chief investigator.

David Schulke, investigator.

Christopher Jennings, professional staff member, Special Committee on Aging, U.S. Senate, room SDG-33, Dirksen Senate Office Building, Washington, DC 20510.

On behalf of the deponent:

Richard J. Riseberg, Esq., chief counsel, Public Health Service, room 6-57, Parklawn Building, Rockville, MD 20857.

Mr. MICHIE. We are on the record.

My name is James Michie. I am chief investigator on the Special Committee on Aging, U.S. Senate. This meeting is now convened. The first session was held on August 26, 1986, in room SDG-31, Dirksen Senate Office Building.

Present are David Schulke, committee investigator, Christopher Jennings, committee staff person, the notary public and stenographer, Albert Sparks, and Dr. Enrique Carter, Director of the Office of Health Technology Assessment in the National Center for Health Services Research and Health Care Technology Assessment, U.S. Public Health Service.

Dr. Carter is accompanied by Richard Riseberg, chief counsel for the U.S. Public Health Service.

On August 15, Dr. Carter was served with a subpoena and notice of deposition authorized by Senator John Heinz, chairman of the Special Committee on Aging, for the purpose of being deposed by committee staff on August 26, 1986.

Dr. Carter did appear here in the committee offices on that date, but declined to be sworn for testimony on the advice of Mr. Riseberg.

Following his receipt of a letter dated August 28, 1986, from Senator Heinz, chairman of this committee, to Mr. Riseberg, in which the chairman overruled Mr. Riseberg's objections, Dr. Carter agreed to return here today and be sworn for testimony.

A copy of the August 28, 1986, letter to Mr. Riseberg from Senator Heinz will be made a part of the deposition record.

Prior to being sworn in, Dr. Carter, I want to remind you that if you knowingly provide false testimony under oath, you may be subject to prosecution for perjury.

66-836 0 - 87 - 12

Are you ready to proceed?

Mr. RISEBERG. I would like to make a statement for the record.

Mr. MICHIE. For the sake of saving time, Mr. Riseberg, we will make your statement a part of the record.

Mr. RISEBERG. OK——

Mr. MICHIE. Are you ready to proceed?

Mr. RISEBERG. I do have one additional paragraph, in addition to what I have said at previous depositions.

Mr. MICHIE. We will make your statement a part of the record. Is the deponent aware of your statement?

Mr. RISEBERG. Right. I also wish to——

Mr. MICHIE. Well, for the sake of saving time, Mr. Riseberg, we will make it a part of the record.

Mr. RISEBERG. No, but I have something else to add.

Mr. MICHIE. Oh, this is something new?

Mr. RISEBERG. Right. I wanted to make——

Mr. MICHIE. Since yesterday?

Mr. RISEBERG. Right, yes.

Mr. MICHIE. And the deponent is not aware of it?

Mr. RISEBERG. No, he's aware of it.

Mr. MICHIE. Well, then we will make it a part of the record.

Mr. RISEBERG. No.

Mr. MICHIE. Would the witness please state for the record——

Mr. RISEBERG. No, no.

Mr. MICHIE. Please. Are you objecting?

Mr. RISEBERG. Yes. I would like to add just one paragaph to the record.

Mr. MICHIE. Your objection is duly noted and it will be referred to the chairman for disposition.

Thank you.

[The prepared statement of Mr. Riseberg follows:]

The Department has asked me to indicate that it is volunteering to make Dr. Carter available in order to cooperate with the Senate Special Committee on Aging in connection with its study of issues related to dialyzer reuse, and that Dr. Carter is participating in today's interview solely on that basis.

He has been advised by attorneys for the Department that the subpoena served upon him is of doubtful legality and that the Department does not regard his participation to be compelled by the subpoena or governed by its terms. Nevertheless, subject to this understanding, he looks forward to answering any questions you may have.

An issue has arisen at some previous interviews as to the authority of the notary public to administer the oath to the witness. While the Department continues to believe that under the standing rules of the Senate only the Chair or a member of the committee has authority to swear in a witness, in order to cooperate with the committee and avoid further delay in getting to the committee's substantive concerns, Dr. Carter has agreed to take the oath in question without conceding to it any legal significance it does not otherwise have. In so doing, Dr. Carter has asked me to emphasize that, whether or not sworn, he would answer truthfully to the best of his knowledge.

EXAMINATION BY THE CHIEF INVESTIGATOR FOR THE SPECIAL COMMITTEE ON AGING

By Mr. MICHIE.

Q. Will the witness state for the record his full name, age, and current home address?

A. My name is Enrique Carter. I am——

Mr. MICHIE. Pardon me just a moment.

Would you please administer the oath.

Whereupon, Enrique D. Carter, having been first duly sworn by the notary public, was examined and testified as follows:

By Mr. MICHIE.

Q. Would the witness please state his full name, age, and address, home address, please?

A. My name is Enrique Delano Carter. I am 41 years of age. My address is 4 Marcus Court, Rockville, MD 20850.

Q. Dr. Carter, have you in fact received a copy of the August 28 letter from the chairman of this committee to Mr. Riseberg?

A. I'm not sure.

Q. We will give you a copy at this time.

A. I am aware of what document you refer to.

Q. And if you would like to take a moment, you can certainly read it.

Mr. RISEBERG. During that period, I wish to add for the record, due to the official business this afternoon——

Q. Have you read this letter?

Mr. RISEBERG. Dr. Carter and I will have to leave promptly at noon.

For that reason, you know, we suggested convening at this early hour, and will be happy to return at a mutually convenient time if we do not finish today.

Mr. MICHIE. Fine, Mr. Riseberg. Thank you.

By Mr. MICHIE.

Q. So you are aware of the chairman's rulings?

A. Yes, sir.

Q. Those two being that the subpeona served on you was in fact a valid subpoena and, secondly, that the oath that you have just taken is indeed a valid oath. Is that your understanding of the letter?

A. I understand that—I have read the letter and understand the statements contained in the letter and the chairman's objections to the——

Q. The chairman's rulings.

A. [Continuing.] The chairman's rulings regarding the positions we took in the August 26 deposition.

Q. Are you a Public Health Service officer?

A. That is correct, yes, sir.

Q. For how long a time have you served, and what is your rank?

A. I am a commander, 05. I have been on active duty with the Public Health Service since July 1, 1973.

Q. Briefly, if you will, what is your academic and training background, Dr. Carter?

A. I attended undergraduate school at Gonzaga University in Spokane, WA. I earned a bachelor of science degree in biology. I subsequently attended the University of Washington School of Medicine, where I earned a doctorate of medicine in 1973.

I pursued an internship in internal medicine in San Francisco at the U.S. Public Health Service Hospital University of California program, and subsequently did a residency in internal medicine in the same program.

I subsequently did a 2-year fellowship in gastroenterology at the University of Washington in Seattle, and have worked as a director of emergency services at Seattle Public Health Service, associate clinical faculty at the University of Washington, and chief of gastroenterology at the San Francisco Public Health Service Hospital, and have had numerous appointments since then in the Public Health Service in terms of Director of Medical Services for various programs, and I am currently the Director of the Office of Health Technology Assessment, U.S. Public Health Service.

Q. Thank you.

For the sake of saving some time, we will during the course of this deposition refer to your agency as the NCHSR; the Office of Health Technology Assessment as OHTA, a component of NCHSR; the Food and Drug Administration as FDA; the Center for Disease Control as the CDC; the National Institutes of Health as NIH; the Health Care Financing Administration as HCFA; the Public Health Service as PHS; the Department of Health and Human Services as the Department; Arthur D. Little, Inc., as ADL.

The OHTA is a component of NCHSR, and performs health technology assessments primarily for HCFA. Is that correct?

A. That's correct.

Q. For how long a time have you served as Director of OHTA, and would you briefly describe your responsibilities?

A. I have been Director of OHTA since 1984, or 1983, I believe. No, I am sorry. 1983. About 3 years.

And my—our—responsibilities are to conduct technology assessment and to make coverage recommendations primarily for the Health Care Financing Administration and for other federally reimbursed health care programs such as, OCHAMPUS, DOD.

Q. Is Dr. John Marshall Director of NCHSR?

A. Yes, sir.

Q. For how long a time have you served under him?

A. Since about the spring of 1983.

Q. What is the approximate number of health technology assessments over which you have presided at OHTA?

A. I believe——

Q. Just approximately.

A. I believe approximately 26 per year for the last 3 years or so.

Q. On average, how many months does it take for OHTA to conduct a health technology assessment, including the research, analysis and drafting of the report?

A. In 1985, it was 9.2 months for a completion of the average assessment from referral. Prior to that time, it had been 10.4 months, and before that 24 months, prior to my tenure at OHTA.

Q. To your knowledge, has NCHSR ever received request from HCFA to conduct a health technology assessment on the reprocessing and reuse of dialysis devices?

A. To my knowledge, no, sir.

Q. Were you aware prior to the March 6 hearing that Dr. Donald Macdonald, the then Acting Assistant Secretary for Health, had requested the NCHSR to conduct an assessment of the safety, efficacy and cost effectiveness of dialyzer reuse within 60 days? Were you aware of that at that time?

A. I'm sorry. Could you repeat the question?

Q. Were you aware prior to March 6, the date of the hearing, this committee's hearing on dialysis device reuse, that Dr. Donald Macdonald, who was then the Acting Assistant Secretary for

Health, had requested the NCHSR to conduct an assessment of the safety, efficacy, and cost effectiveness of dialyzer reuse within 60 days?

A. Prior to March 6, let me say that prior to March 6, I was not aware that the request had taken place. I was aware that a request was likely to occur prior to that time.

Q. Let me share with you a copy of a March 5, 1986, memo to Dr. Marshall from Dr. Macdonald. The subject of this one-page memo, "Reuse of Dialysis Supplies."

In this memo, Dr. Macdonald requests that the NCFSR conduct an assessment, isn't that correct?

A. I am sorry. I was reading the memorandum. You said he requested in this memo?

Q. In this memo, doesn't he request that NCHSR conduct an assessment of dialysis device reuse?

A. Yes, sir.

Q. The memo states that the reuse of dialyzers has never been assessed by the PHS. To your knowledge, was that a correct statement at this time?

A. To my knowledge, I was aware—I was aware at that time that there had previous committee action on the issue, but in terms of a formal assessment along the lines that we conduct, to my knowledge, I was unaware of any prior such activity.

Q. This memo further states:

> There is a need to assess the clinical and cost tradeoffs between single and multiple use the the dialysis filters. The importance of this issue dictates a timely analysis.

Now, in early March, when Dr. Macdonald generated this memo, what was your undertanding at that time concerning his statement that the importance of this issue dictated a timely analysis?

A. I had not seen this memorandum at that time, sir.

Q. Did anyone convey to you that understanding, either on March 6 or 7?

A. I'm sorry. Specifically, what understanding are you referring to?

Q. Did anyone convey to you the need to conduct this analysis in a timely way?

A. Now, to the best of my recollection, I recall I was told that we would have a request for an assessment forthcoming and that the turnaround time would be expected to be in the vicinity of 60 days.

Q. OHTA was assigned to conduct the assessment, isn't that right?

A. That's correct.

Q. Did Dr. Marshall give you that assignment?

A. Yes, sir.

Q. Did you from the start take an active role in the assessment?

A. Yes, sir.

Q. Did Martin Erlichman, a health science analyst on your staff, have a primary role in the conduct of the assessment?

A. Yes, sir.

Q. Referring back to Dr. Macdonald's March 5 memo to Dr. Marshall, Dr. Macdonald made the following request: "Please complete a review to provide me with your conclusions with respect to the safety, efficacy and cost effectiveness of dialyzer reuse within 60 days."

At that time, when you first received the assignment for OHTA to conduct this assessment, did you, and you were told it would be done in 60 days, did you raise the question to Dr. Marshall about whether it could be done in that short length of time?

A. I don't recall when the question was specifically raised. I knew it was, but I don't recall exactly whether it was at this time or shortly thereafter that it was raised.

Q. You believe shortly thereafter?

A. Yes.

Q. Approximately how soon after? A week, 2 weeks, a matter of days, do you think?

A. I think it may have been within the order of a week or so. I am just trying to recall the specific chronology of these events. I don't—I think it was—it was a short time, I know that. It was probably within a week or so.

Q. When you did raise this question, what was Dr. Marshall's response? Do you recall?

A. I believe he indicated that he would seek further—more time for the completion of assessment by requesting of the actual extension of the due—due time.

Q. If it was needed?

A. I don't recall him indicating that but I am certain he indicated he would request an extension from the Acting Assistant Secretary for Health.

Q. Did you question this short timeframe repeatedly during the period from March 7 or, as you said, within a week or so from March 7, through June 9 of this year? Did you have occasion to question it again?

A. Oh, certainly, yes.

Q. You did.

Roughly how many times would you say you brought up this question during that period up to June 9?

A. I really don't know. I just know that we proceeded to develop the Federal Register notice and proceeded working on it, fully, in my judgment, aware that we might not meet that deadline.

Q. In light of the fact that the average assessment, last year anyway, took 9 months or more and the previous year 10 months or more, did the timeframe of 60 days, or even 90 days at that time, seem to be unreasonable to you?

A. All I can say is that I know it was a fairly short time. It was much shorter than our normal——

Q. Much shorter, was it not?

A. Yes.

Q. In fact, you were asked to do an assessment in less than a third of the time that you ordinarily take in time to do an assessment of that nature; isn't that correct?

A. It would appear it would seem so. I don't—I think that is probably correct, yes.

Q. Did this concern you?

A. Well, I—my main concern is in doing a credible job of all assessments we——

Q. And a thorough job?

A. And thorough job, yes.

Q. And an objectivity job?

A. We always do an objective job when we approach these assessments, at least in OHTA.

Q. Referring again to Dr. Macdonald's March 5 memo, the third sentence in the first paragraph states, quote, "The cost implications of the variance in current practice for use of dialysis supplies are of interest to HCFA and the Congress as well as to PHS."

Now, I have taken some liberty to paraphrase, but do you read it to mean that, what I just stated: "The cost implications of the variance in current practice for the use of dialysis supplies are of interest to the HCFA and the Congress as well as to PHS"?

A. I am not sure I even understand what cost implications of the variance means. I really don't know. In that particular context, I don't know what implications of the variance refers to, but I see here that it says that cost implications are of interest to HCFA and the Congress.

Q. Were you made aware at the outset of the assessment or any time thereof of why HCFA was interested in these cost implications?

A. I didn't have this memo. I don't know—it wasn't a question that occurred to me in the conduct of the assessment.

Q. But did anyone during the course of the assessment at any time tell you why HCFA was interested in this assessment?

First of all, did anyone tell you that HCFA was interested in the assessment, in fact took great interest in the assessment?

A. I, in all honesty, was unaware of the interest, specifically, in our assessment.

I believe I recall being casually asked on one or two occasions by staff people in HCFA that they heard we are doing an assessment and how is it going.

But I don't recall any direct interest in this assessment vis-a-vis HCFA. I knew that we were doing it at the request of the ASH, I assume for the Secretary, in response to the congressional activity that had previously transpired on March 6 in testimony by the Department, but I was not directly aware of any direct relationship between the assessment at that time and HCFA. I just——

Q. What about later, though, as the assessment proceeded, during the course of the assessment?

A. I don't think so.

I recall that we have had occasion to note the fact that this was not an assessment referred by HCFA, since all of our assessments are either referred by HCFA or CHAMPUS. It is slightly unusual in that regard.

So I did—I did not connect up this assessment with HCFA in terms of us providing them with a recommendation or anything, which is what we usually do with an assessment.

Q. Did there come a time during assessment when you became aware that HCFA had a pending proposed regulation to reduce the reimbursement rates for dialysis?

A. Oh, yes, I was aware some time during the conduct of the assessment that—I was aware before the assessment that—it was started, even, that those—that HCFA was conducting such an activity.

Q. You were?

A. But since they never contacted me—us—directly in relation to this assessment, we, in keeping with our policy, we are purely relative, mostly, and we're not—didn't go out to invite participation in that reimbursement activity on HCFA's side, at least not through our office.

Q. In such a case, isn't it your procedure, in fact, not to get involved in discussions with that agency, simply because, if you did it, there might perhaps be a conflict of interest?

A. Well, let me—let me—let me say—during the conduct of the assessment?

Let me—ordinarily, we don't, but to begin with, in a decision to conduct an assessment, there is a physicians' panel at HCFA in which our physician staff, there are seven physicians on our staff who attend those meetings and participate in the panel's deliberations that result in the referral.

And, following that, the only instance in which we might go back to HCFA would be for a request for clarification of the question when they make the formal referral to us for the assessment.

But to answer your question, no; we do not usually discuss the matter at HCFA once we have started the assessment, because I think it is our policy that we try to prevent any undue influence on the evolution of these reports as we generate them.

Q. Now, you stated a little earlier that, just a moment ago, that you in fact were aware of HCFA's activities in this proposed regulation to reduce the reimbursement rates, correct?

A. Yes.

Q. Was Dr. Marshall aware of this activity prior to the assessment and the hearing?

A. Well, I think that in preparation for the March 6 hearings, I believe—I know of my own knowledge—that I became aware of those developments at that time, some time late in February.

Q. Wasn't this at a meeting with various individuals, including individuals from HCFA in preparation for the hearing?

A. I don't recall such a meeting. At least I didn't participate in such a meeting, or attend one.

Q. But do you know if Dr. Marshall was made aware of this prior to the hearing?

A. He would have been through our briefing process, since he was the witness for the committee, and I recall in preparing the testimony addressing a range of issues, among which—one of which—was that the cost implications of reuse and the fact that rates were ratcheted down, and that that had an effect in some people's thinking on the tendency to reuse.

So, that, yes; the answer is yes. I was aware of that thinking at that time, and Dr. Marshall would have been aware of it since we would have discussed it in preparing for the testimony.

Q. Did any mention of HCFA's activities regarding the proposed regulation to reduce the reimbursement rates for dialysis, was there any mention of that in Dr. Marshall's prepared testimony?

A. I don't remember. I think—I vaguely recall that there was—there may have been a statement to the effect that—I would like to refresh my memory——

Q. Please do.

A. Because I really don't remember, and——

Q. You did—you did help him, assist him, in preparing his testimony, didn't you?

A. That's correct.

I fail to see direct mention in the testimony of that particular point that you raise.

Q. Thank you, Dr. Marshall—Dr. Carter. Forgive me.

NCHSR published an April 10—I'm sorry, Dr. Carter. Have you finished reviewing? I don't mean to——

A. [Witness hands to Mr. Michie.]

Q. The next question is, NCHSR published an April 10, 1986, Federal Register notice which announced the assessment of dialysis device reuse and solicited public comment on that issue. Is that correct?

A. That's correct.

Q. What was the original deadline for NCHSR to produce a draft report on this assessment?

A. I believe 60 days from the date of publication of the notice, we indicated in the Federal Register. It would have been June 10.

Q. What was the deadline for submitting comments in response to NCHSR's April 10, 1986, notice?

A. The deadline would have been the same deadline stipulated in—I'm sorry. I think I misunderstood your—your original question.

What I was answering is this question. The deadline for submitting comments would have been April 10. It would have been—I'm sorry—June 10.

Q. June 10, the draft report?

A. That's correct.

Q. And what about the comments?

A. The comments would have been—I'm sorry. I think I'm still confused about—by—the question here.

If you are saying, if you are asking what was the deadline for submitting comments, that was 60 days from the date of publication, which would have been June 10.

If you are asking what was the deadline for the—the due date for the report, I believe——

Q. The original due date for the report.

A. I seem to remember we originally had a June 2 date, and then, I believe, June 13.

Q. Do you recall Senator Heinz having submitted to NCHSR on June 9, 1986, a voluminous response to the April 10 notice?

A. Yes, sir.

Q. Did Senator Heinz' submission affect in any way the timetable for completing the assessment?

A. Well, certainly, we invariably will incorporate material received in the conduct of our assessments.

While we may have a comment period, and we stipulate the minimum amount of time available for submitting comments, but it does not preclude our using information received after that time.

Ordinarily, we use all information up until the completion of a report, that is received, and so in this instance it was certainly a voluminous enough submission that we—it required a significant amount of additional time to review and analyze the package——

Q. Was anything learned from these documents?

A. Yes.

Q. That was found to be significant, or important to the assessment?

A. Oh, yes, I would say so.

Q. Can you recall an example or two?

A. There were—there were memoranda in the—the establishment investigation reports pertaining to events in various facilities involving either pyrogen reaction or, I should say, adverse reactions to patients undergoing dialysis.

There were—there were correspondents that—I'm sorry. I don't have the list in front of me of materials received, but there were—there were, yes.

Q. Nonetheless, there were significant items in there that you had not been made aware of prior to that?

A. There were significant items that I had not seen previously, yes.

Q. I have here for your reference a June 10, 1986, memo to Dr. Donald Newman, Under Secretary of the Department, from Dr. Macdonald, then Acting Assistant Secretary for Health, the subject of which is "Reuse of Hemodialysis Devices."

At the bottom of page 2, you will note that this memo was prepared by Dr. Marshall. Can you see that on the second page? Does it state it was prepared by Dr. Marshall——

A. Yes.

Q. [Continuing.] On page 2,

A. Yes.

Q. In item number 5 on page 2, beginning with the second sentence, it states, "The assessment will be completed on June 10, and will be transmitted with recommendations to HCFA at that time. NCHSR, HCTA have found no evidence contradictory to the position which we took in testimony."

As a person intimately familiar with the assessment, closely involved in this assessment, you supervised it, what would you say was the basis for that statement of Under Secretary Newman?

A. I don't know.

Q. At the time that this memo was generated, did Dr. Marshall ever ask you for your opinion? Was this your opinion at that time, that nothing new had been—been found?

A. Well, I was—to be honest with you, I was unaware that the memorandum was being written. I didn't know that this had been sent forward.

Q. But in light of your having received all those documents and then, of course, in light of you and two of your staff members having visited here on April 17, and we will get into that in more detail later, but in light of your discoveries during your review of this committee's files on its investigation, how could Dr. Marshall have made this statement at that time?

A. You will have to ask Dr. Marshall because, as I indicated, I was not privy to the development of these positions during this time.

Q. I understand, but based on what you knew as of June 10, would you say that this at that time was a true and accurate statement, that no new evidence contradictory to the position which Dr. Marshall had taken in his testimony had been found?

A. I don't—I'm not sure what position, what position he is referring to here. Having been involved in the preparation of the testimony, there are numerous things cited and alluded to in the testimony, so I am not sure specifically what position he was addressing in this.

Q. Let me put the question to you this way. If Dr. Marshall had come to you on June 9, or June 6 when he drafted this memo, first drafted it, and he had asked you. "Dr. Carter, I have to draft this memo. It's going to go to the Under Secretary. What shall I tell him? Do we have anything new? Do we know anything at all with regard to our testimony? Do we know anything new that would have changed our testimony in any way on March 6, or that would have added to it, or that would have taken away from it?"

What would your advice have been to him at that time? Would you have advised him that, "Dr. Marshall, I don't think we have any new evidence"?

A. Well, it depends on which specific issue, because in the testimony there were numerous issues that were raised.

Q. I understand, but this statement——

A. You said that the formaldehyde, formaldehyde safety, for instance. I would have to say that at the time this memorandum was written, I would have said that we probably didn't know much more than about formaldehyde than we knew at the time of the testimony in March.

Q. No, I understand, but this statement, though, covers all of the testimony.

At that time, didn't you, having visited here, after having reviewed the material on the Deane report and so on, didn't you at that time prior, a month prior, more than a month prior, to when this memo was written, didn't you have new information that at the very least would have brought into question Dr. Marshall's using Dr. Deane's report, Multiple Use of Hemodialyzers, to support his contention that reuse was safety?

A. Oh. Why, if you mean—I see. I see the question you are getting at.

If you mean that from the time the testimony was written to the date this memorandum was prepared, if we learned anything new that we did not know as of the time of the testimony, I would say—I would say yes, we did learn new things that we did not know at the time the testimony was prepared and delivered before the committee; yes.

Q. And, so, therefore, Dr. Marshall's statement in this memo that he prepared that his agency had found no new evidence "contradictory to the position which we took in testimony," was that an accurate statement as of June 10?

A. While it could have been Dr. Marshall's impression, as I just indicated, there had been new knowledge, at least I had gained new knowledge, so that while Dr. Marshall may have entertained this impression, it wouldn't—it certainly wasn't my impression.

Q. Now, if he had come to you at that time and asked you, "Dr. Carter, how do you think I ought to phrase this?" would you have phrased it the way he did here, if he had asked for your advice?

A. You see, I am trying—one of the reasons I am thinking here, I am trying to remember. This was June——

Q. Ten.

A. June 6 to 10 that this was done?

Q. The memo is dated June 10?

A. June 10, and it was drafted on June 6.

Now, you might recall that much of the new information that—in the conduct of the assessment, we generated new information, but—but a significant amount of information, new information, as you just pointed out, came to us from the committee on June 9, and so that on June 10 I had not personally made significant progress in the review, although I had made a sufficient progress to know that we weren't going to be able to finish the report.

Q. I understand, but what my question is, again, is simply this:

If Dr. Marshall had come to you prior to clearing this memo to go forward, this memo dated June 10, and if he had asked you, "Dr. Carter this, sentence here, the one about we having found no evidence contradictory, is that satisfactory with you? Would you word it that way? How would you word it, Dr. Carter?" What would you have told him?

Would you have said, "That's fine, Dr. Marshall," bearing in mind, I think you can recall, will you not, that prior to June 9, you had been informed by a staff person of this committee, David Cunningham, of a series of outbreaks of infections at dialysis clinics beginning in early April. Let's also put that into perspective.

A. Well, at that time, I don't recall the date that that occurred, but I think it was around the time of the submission of the material, which would have been probably within the timeframe that this memo was being framed. I was made aware that that was one of the items that I would include under new information that we had become aware of.

Could you rephrase the question again?

Q. Once again, I am asking you, if Dr. Marshall had come to you before finalizing this memo, this memo dated June 10, and had asked you whether or not you agreed with his phrasing here, his language here about NCHSR not having found any evidence contradictory to the position taken in the testimony, would you have said, "Fine, Dr. Marshall, I don't see any problem with that, you can go with it," or would you have suggested a modification?

A. Well, this was—I think that—I don't know the circumstances under which the memorandum was written, you see, and so, personally, this would not have been a statement that I would have generated at that time, give the fact that, as you pointed out, we were made aware of new information at this time.

But this may have been Dr. Marshall's impression at that time.

Q. Are you aware that on June 9, I telephoned Dr. Marshall to inform him that Senator Heinz' comments were on their way and were being hand carried to you—to him—by Mr. Cunningham, a member of this staff?

A. Yes; I was aware of that.

Q. And did Dr. Marshall also make you aware at that time that I had informed him, or had asked him in that telephone conversation, whether or not he was aware of the infection outbreaks?

A. I believe he had asked us about that, because—and I think we indicated that we were aware of it at that time.

Q. Prior to that?

A. Yes.

Q. You had been made aware of it prior to my having made him aware of it. Isn't that correct?

A. I—yes, that is correct.

Q. So, bearing all of that in mind, if Dr. Marshall had come to you, and if I understand you correctly you were not aware that he had generated this amendment—is that correct?

A. That's true.

Q. If he had come to you and asked you if that phrasing was correct, or should it be modified, would you have modified it? Would you have suggested to him that he modify it?

A. At that time, I probably would have. I—based on the information I had then—I would have.

Q. Getting back to—getting back to your visit to these committee offices on April 17, I believe you were accompanied by Mr. Erlichman and Dr. Handlesman, is that correct?

A. That's correct.

Q. And that was on April 17 of this year, is that correct? Is that your recollection?

A. Could it not have been March, a month prior to that?

Q. Our records show April 17.

A. It was a short time following the testimony that we were invited in to review some materials that were available to the committee that we did not at that time have in our possession.

Q. Anyway, it was some time after the hearing?

A. It was after the hearing.

A. March, perhaps April.

Is it your recollection that you or someone else on your staff made two visits here?

A. Two visits?

Q. I'm just asking. Do you recall, or was it one visit?

A. I recall that we made one visit here that Dr. Handlesman, Mr. Erlichman and I came here on one—on one day at your request which Dr. Marshall had indicated to us we could feel free to do in terms of getting the information the committee had volunteered to provide.

Mr. MICHIE. We will take a 5-minute recess, please.

[Recess taken.]

Mr. MICHIE. All right, gentlemen. We are on the record.

By Mr. MICHIE.

Q. Dr. Carter——

Mr. RISEBERG. Do you want some water?

The WITNESS. Please.

By Mr. MICHIE.

Q. Dr. Carter, did you as Director of the OHTA perform an objective, thorough and objective assessment of reuse——

A. Yes, sir.

Q. Were you aware that Dr. Marshall informed Dr. Macdonald, Assistant Acting Secretary of Health, on or about March 7, 1986, the day after the hearing, that the substantive part of your analysis had been completed and that there would be nothing new to be found regarding the issue of reuse?

A. What date, on what date, sir?

Q. That was on March 7. Were you aware that Dr. Marshall had informed Dr. Macdonald about that on March 7?

A. No.

Q. Let me share with you a note dated March 7, 1986, and stamped "Confidential." This is from Dr. Marshall to Dr. Macdonald, the subject of which is "Dialyzer Reuse." Please take a moment to examine the memo.

Take your time, but let me know when you have finished reading the memo, please.

Are you finished?

A. Yes, sir.

Q. Had Dr. Marshall shared this memo with you at that time?

A. No, sir.

Mr. MICHIE. Mr. Schulke, would you please read the entire note into the record. This is a note from Dr. Marshall, is that correct, to Dr. Macdonald?

Please read the entire document.

Mr. SCHULKE. On the letterhead of the Department of Health and Human Services, National Center for Health Services Research and Health Care Technology Assessment, dated March 7, 1986. "Note to Dr. Macdonald," stamped "Confidential." "Subject: Dialyzer Reuse."

"Prior to today's hearing with Senator Heinz on this subject, I had assumed that we would carry out the assessment within the 60-day period that was specified in your March 5 memorandum.

"However, the original plan was to have used this as a way of deferring a response to the Senator.

"Unfortunately, it was decided that I should promise in the testimony to carry out this assessment. This means the process will be carried out under the careful scrutiny of committee staff, probably Mr. Michie.

"The substantive part of our analysis is completed. We had to do that for the testimony. There is nothing new that will be found. But, because of the sensitivity of this, and the activation of constituency groups as a result of these hearings, I think it best that we be allowed 90 days for carrying out the study. That will allow time for following our formal processes which includes a notice to the Federal Register and solicitation of comments from the cognizant specialty and subspecialty groups.

"In this case, we will probably solicit comments from the patient groups as well. They won't have facts to give us, but will give us strident opinions.

"I don't expect that Mr. Michie will perceive this study as anything but a whitewash, and consequently that will be the Senator's view, but I think we will at least forestall some criticism by going to 90 days.

"If you concur, I will send you a formal request for an extension, without any of this background."

Signed "John E. Marshall, Ph.D., Director."

By Mr. MICHIE.

Q. Dr. Carter, why do you think Dr. Marshall felt it necessary to stamp this note confidential?

A. I have no idea, sir.

Q. Do you have any idea as to why he didn't share this note, this information, with you on March 7?

A. No, sir.

Q. Do you think he should have?

A. Well, I must say that I am not always privileged to communications between Dr. Marshall and the Assistant Secretary, so that while it may not have been unusual for it not to have been shared with me——

Q. What I mean by that is the content of the memo, the content of the memo itself. Did Dr. Marshall at any time on March 7 or thereafter share the information contained in this memo with you?

A. No, sir.

Q. Again referring back to this memo, do you have any knowledge of the original plan, as Dr. Marshall called it, as a way of deferring a response to Senator Heinz?

A. No, sir.

Q. Do you have any idea what he meant by that?

A. I do not, sir, no.

Q. Why would Dr. Marshall have found it unfortunate, as he put it, to have promised in testimony to conduct the assessment? Do you have any understanding at all of that?

A. Well, I am reading this memorandum here trying to gain some understanding of the question—of the answer to that question. It is confusing.

Mr. RISEBERG. Have you ever discussed this memo with Dr. Marshall?

Mr. MICHIE. Excuse me.

Mr. RISEBERG. You are asking him to speculate about what was going through Dr. Marshall's mind.

Mr. MICHIE. I am not asking him to speculate. I am asking him if he had any understanding at all what that meant, and that's not asking him to speculate.

A. The answer is no, sir. The answer is no.

Mr. MICHIE. If you wish to register an objection, please do so.

Mr. RISEBERG. I object.

Mr. MICHIE. Your objection is duly noted and will be referred to the chairman for disposition.

By Mr. MICHIE.

Q. Why would Dr. Marshall be concerned about the careful scrutiny, as he put it, of the assessment process by this committee's staff? Why would he be concerned about that? Do you have any idea?

A. I don't know that he expressed concern other than it was stated here. "This means the process will be carried out under the careful scrutiny of the committee staff, probably Mr. Michie." I don't read this statement to be an expression of concern.

Q. Just a matter of fact?

A. Well, it's a statement. I don't know what underscores that statement, sir.

Q. Fine.

How could NCHSR possibly have completed the substantive part, as Dr. Marshall put it, of the assessment as early as March 7, when NCHSR had not even published the Federal Register notice seeking any and all information from the public, from the dialysis industry, from the scientific community, from the Federal agencies, regarding the safety and efficacy of the reprocessing and reuse of dialysis devices? How could he have stated that at that time?

A. How could——

Q. How could he possibly have stated to Dr. Macdonald that the substantive part of the assessment as of March 7 had been completed, when in fact the Federal notice had not even been published yet?

A. Is that a statement, sir, or is there a question that——

Q. My question to you is, on March 7, Dr. Marshall informed Dr. Macdonald that the substantive part of the assessment had been completed. Do you read that there? do you see that?

A. Yes, sir.

Q. And then—but then—as you know, the Federal notice had not been published until April 10, was it?

A. Yes, sir.

Q. And that Federal notice sought any and all information from the public, the scientific community, the Federal agencies involved regarding safety and efficacy of reuse. Isn't that correct?

A. Yes, sir.

Q. How could Dr. Marshall have known, then, on March 7 that the substantive part had been completed?

A. Well, I cannot answer that question, sir, because I really don't know the answer to the question.

But I must add, though, that the following statements, or sentence said, "We had to do that for the testimony," which implies that Dr. Marshall may have labored under the impression in making that statement that in preparing our information base for the testimony, that what we had incorporated there was all the information that existed at that time.

Clearly, there were new data that we became aware of, as you indicated earlier in these proceedings, that we subsequently became aware of, that at the time of the date of this letter I certainly was not aware of. So——

Q. Then he goes on to state, "There is nothing new that will be found."

How could he possibly have made such a definitive statement in this memo dated March 7 when NCHSR had not even published its Federal notice seeking information?

A. I really don't know.

Q. If Dr. Marshall had come to you on March 6, the day he obviously drafted this memo, because he states in the first sentence, "Prior to today's hearing," and as you recall the hearing was on March 6, isn't that right?

A. Yes, sir.

Q. If he had come to you on March 6 and asked you to review this memo, would you have told him that this memo was fine with you and that you felt it was proper information to be given to Dr. Macdonald?

A. Well, he hadn't brought the memo to me, so——

Q. But if he had. If he had. If he had shown you this memo wherein he states without qualification, "There is nothing new that will be found?"

A. You are asking me to speculate on a point that—oh, in regard to that specific statement?

Q. Yes.

A. Oh, no. I can never say that nothing new will be found when we embark upon the conduct of an assessment, because the very purpose of the assessment is to discover all available information.

Q. And as you did on April 10, you published a Federal notice, a notice in the Federal Register seeking any and all information from all entities who might have knowledge of the reprocessing and reuse of these devices, isn't that correct?

A. That is correct.

Q. So bearing that in mind, would you have suggested at that time, if he had shared this memo with you, that he could not have possibly made that statement, "There is nothing new that will be found" on March 7 to Dr. Macdonald?

A. Well, I personally never suggested that.

Q. Would you have made that statement to Dr. Macdonald?

A. Would I have made that statement?

Q. Right?

A. No, sir.

Q. Why not?

A. Well, by very nature of the assessment—the very nature of the assessment process—we do not know what all available information consists of, or we would not have to perform an assessment.

We invariably seek new information and usually find information, and so, no, I wouldn't make that—have made—that statement to Dr. Macdonald.

Q. That is sort of putting the cart before the horse, isn't it, so to speak, reaching a conclusion before you even seek out the information in order to conduct an assessment?

A. I would say that, again, I don't know what Dr. Marshall's frame of mind was at that time and, as I indicated, it was very possible that he was under the impression that during the time that those of us who worked on preparing the testimony conducted that process that we had available to us of the existing information that there was to formulate the basis for his testimony.

So in one way, I would—I can understand how he may have been of that frame of mind.

Q. Now, if you will look back at the June 10 memo that Dr. Marshall drafted for Dr. Macdonald's signature, I think it is sitting right there in front of you, the second page, the language we went over, isn't that quite similar to what is stated in his confidential memo to Dr. Macdonald on March 7 about there being no new evidence?

In the March 7 memo he says nothing new will be found, and in there he says there is no new evidence. Isn't that similar?

A. I am sorry. What paragraph are you reading from, sir?

Q. That's down toward the bottom there, the language we went over a little while ago, where he says, "There is no new evidence to contradict the testimony." Do you see that sentence?

A. Yes, sir.

Q. Isn't that quite similar to what he stated to Dr. MacDonald on March 7?

A. Well, whether or not they are similar may be a matter of interpretation, but——

Q. Fine. What is your interpretation?

A. Well, again, since I—I really am not—I don't know what Dr. Marshall's frame of mind was at that time and what information he was laboring on—under—at the time these memos were prepared, and since I was not privy to the development of these memos, I really cannot speak to what similarities underscore the thought behind these statements.

Q. Fine. That's fine.

Now, why—how—why do you think and how do you think—why do you think—Dr. Marshall would have predicted in his March 7 memo that Senator Heinz would take this assessment, the assessment that was performed, and characterize it as a whitewash? Why would he predict that?

A. I don't know.

Q. When did you first become aware of infection outbreaks in dialysis clinics in California, Texas, Florida, and Georgia, Dr. Carter?

A. Infection outbreaks.

Q. The first, I think, occurred in California, Inglewood, CA.

A. Yes. I am trying to remember the dates now. I believe in the MMWR, the dates of those occurrences were early June; is that correct?

Q. What I am asking you is, when did you become aware of them, and who made you aware of these infection outbreaks?

A. I believe that the committee, the committee brought to our attention the fact that these developments had been under investigation and we at that time became aware, and I suspect that was some time either in May or late April, some time between April and May, that we bacame aware of these developments in Inglewood, CA, and Daytona, FL, and also Dallas, TX, and Georgia, and subsequent ones in Minnosota, Massachusetts, and Pennsylvania.

Q. At that time, were FDA and CDC, were those two agencies aware that you were conducting an assessment?

A. Yes, sir.

Q. When did they inform you of the infection outbreaks? When did FDA let you know, do you remember?

A. I believe it was in the week of—in June, in late June 1986. I was away at the time, and I believe a memorandum was transmitted to our office indicating that these developments were under investigation.

We were, from the time we became aware of them, we sought to confirm that information through the Centers for Disease Control and the Food and Drug Administration.

So we did pursue, we did follow up on, the information that was brought to our attention about these outbreaks.

Q. So, in other words, you learned from this committee staff of these infections some time in May, but you didn't, you were not notified by FDA until late June. Is that correct?

A. Well, we were—we had verbal confirmation from the Centers for Disease Control and subsequently by FDA by—by telephone conversation, but I don't recall that we received anything in writing to confirm that until late in June.

Q. Did there come a time during the conduct of the assessment when you and Dr. Marshall discussed the level of cooperation in response from the FDA, CDC in providing OHTA with documentation, data and information essential to your assessment?

A. Yes, sir.

Q. And when was this?

A. I believe in May we first discussed that in the context of having received responses from the agencies that were not fully consistent with the information that we had then become aware of that had been brought to our attention outside of the scope of the formal processes by which we request information from the agencies and receive responses.

Q. Did you not in fact receive much of this information, as you put it, outside of the normal channels, from this committee staff?

A. Yes, sir.

Q. Let me share with you now a May 28, 1986, memo to you from Dr. Robert Veiga, Office of Health Affairs at FDA.

Do you recall this memo?

A. Yes, sir.

Q. And this is in response to your April 9 request to FDA for information and data. Is that correct?

A. That's correct.

Q. The memo states, quote, "All information concerning the issue of reuse of hemodialyzers, blood lines, transducer filters and dialyzer caps is already available to OHTA as part of the package prepared for the Senator Heinz hearing. The Office of Device Evaluation has no additional information."

Now, didn't you know at that time that this was not a true statement?

A. Yes, sir.

Q. Didn't you know as early as perhaps even April 17 when you visited with us in these offices, or soon thereafter, that FDA had in fact not shared everything on safety and efficacy on reuse with your agency?

A. Yes, sir.

Q. When did you——

A. Well, at that time, though, I must add that we had a request in to FDA, and so that I don't—there were not conclusions in my mind as to whether or not we were going to receive that information until the time of receipt of this memorandum.

So that I was not aware that, at the time we met, that the information—I knew that we had seen information here for the first time, but I didn't——

Q. I understand. But what I am getting at is, at the time you received this memo, you did have—you didn't know that FDA had reposited in its files documents that had been generated months prior?

A. No, sir.

Q. Even months prior to the hearing on March 6, did you not?

A. Yes, sir.

Q. You knew that, you were aware of that. This committee staff made you aware of that; isn't that correct?

A. I believe so, sir.

Q. And so, when you received this memo, didn't this memo distress you in light of the fact that it was not a true statement?

A. Yes, sir.

Q. And what did you do about it, Dr. Carter?

A. Well, I called the FDA, and I called, I tried to reach Bob Veiga, and I wasn't successful in doing so, so I called Stu Nightingale, who also was not in, and reached Mr.—I am trying to recall who at FDA—I'm blocking on the name of the person.

Q. That's all right.

A. But in any event, I—I—I called and I indicated that this was not acceptable as a response, and that we had received nothing except for the briefing materials at the time of hearing, so that, yes, I was not particularly happy with this response.

Q. In fact, you were angry, were you not——

A. I also brought it to Dr. Marshall's attention at that time.

Q. And you were somewhat angry were you not?

A. Certainly, sure.

Q. And did you bring this to the attention of Dr. Marshall?

A. Yes; I did.

Q. What did he do?

A. I don't recall exactly. Well, he—I think Dr. Marshall's response was one of—he was surprised and he shared my view that this was not an acceptable response.

Q. When did you become aware of the existence of the FDA's Reuse Committee, approximately when?

A. Back in February, during the preparation of testimony.

Q. And isn't that the function and mission of the Reuse Committee, to develop a policy for FDA on the reuse of medical devices, reprocessing of medical devices?

Is that not one of the issues addressed by this committee? What I mean by that are medical devices across the board. Is that your recollection?

A. It is my recollection that this committee had been focusing on hemodialyzers specifically, and I am unclear as to how long the committee had been in existence, but I was aware of it and its mission to evaluate the issues of safety and efficacy or reusing hemodialyzers and what measures, if any, are needed for those who reuse.

Q. Are you aware that FDA had functioning a second committee, the Dialysis Use Committee, concurrently with the Reuse Committee? Were you aware of that?

A. No, sir.

Q. Let me share with you now a copy of the October 23, 1984, report of the Dialysis Use Committee.

You will note that this report addresses several issues concerning hemodialysis, including reuse. In fact, on page 1 of the report, and that's underneath that cover memo, in the second paragraph, I think you find that reuse is listed as one of a number of issues considered by FDA to be of an urgent—the word urgent is used—nature at that time. Do you see that, Dr. Carter?

A. Yes, sir.

Q. Had you seen this report prior to your appearance here today?

A. No, sir.

Q. Attached to the three-page report, please note that there are 39 pages of user-related problems and elaborations including bacterial contamination, inadequate disinfection procedures, toxic materials in the water supply crossing into the bloodstreams of patients, and others.

We are going to supply your agency with a copy of this report.

My question to you is, shouldn't the NCHSR have been provided this report for consideration in the assessment?

Mr. Riseberg. Do you want him to take a look at the report?

Mr. Michie. He is looking at it, Mr. Riseberg, and he can take his time to answer.

A. Could you repeat the question?

Q. In light of the fact that this report contains information about reuse, not solely about reuse, but reuse was among the issues that were discussed in this report, involving bacterial contamination, inadequate disinfection procedures, toxic materials in the water supply crossing into the bloodstreams of the patients and other problems as well, my question to you is, shouldn't the NCHSR have been provided this report by FDA for consideration in the assessment?

A. Well, I—I wish I had seen it before today.

I think that to the extent that it addresses the issues that we were focusing on, and carefully outlined many of the relevant issues, yes.

Q. I have here a June 25, 1986 memo to Dr. Marshall, Director of NCHSR, from James Benson. This, I think you will find, is the memo we were mentioning a little earlier in your testimony, this memo alerting NCHSR to the infection outbreaks and to the recall of the chemical RenNew-D?

A. Yes.

Q. And to the best of your recollection, I think you did state so, but I will state the question again, was this the first written notice to your agency from FDA regarding these matters, to your recollection?

A. I believe that is correct, yes, sir.

Q. Didn't Dr. Marshall bring in to work with him on the morning of August 4 a collection of documents, documents that I had delivered to his home along with a cover letter on August 2, including FDA medical device reports on reuse problems, most, if not all of which, had not been provided to NCHSR by FDA?

A. Yes, sir.

Q. Didn't you at that time suggest to Dr. Marshall that at the very least some of these FDA documents pertinent to the assessment should be appended to the report?

A. I'm sorry. Which documents were you referring to?

Q. The documents that I provided to NCHSR through Dr. Marshall on August 2, the documents having been a collection of medical device reports pertaining to reuse problems.

Do you recall the morning of August 6 when you and I and Dr. Marshall sat in his office and he remarked to me that you had indeed made such a suggestion, but that he had decided that that would not be the best course to take?

A. I think now that you remind me, yes. I didn't recall specifically what documents there were that I suggested be included as appendices, but, yes, the answer is yes.

Q. Did anyone at any time during the course of the assessment state to you, and when I say at that time, at any time—let me correct that.

Did anyone at any time during the course of the assessment state to you or give you the impression that your assessment of dialysis device reuse was not a regular assessment and that it had to be done in a hurry?

Did anyone tell you that or give you that impression?

A. Oh, well, yes. We knew that, but it was also a case that, usually, the assessments come to us from HCFA, and—and so to that extent it was not a regular assessment, and of course the timeframe, we usually do not put a timeframe on the assessments when we start out.

Q. You don't?

A. Well, if we put a notice, we give a 90-day comment period in the Federal Register, but information continues to come in during the 9 or 10 months, 12 months, sometimes, over which we conduct the assessment.

Q. Is it—is it not extraordinary for your agency to have solicited comments in the Federal Register on this very complicated matter? you will agree that it is complicated, is it not?

A. Oh, certainly.

Q. Is it not extraordinary for your agency to advertise in the Federal Register for any and all information, scientific data, and whatever may be out there, published as well as unpublished, to set a deadline, an original deadline, for a report on the same day of final comments? The last day for comments to come into your agency was June 10.

A. Well, we, I suppose——

Q. And is it not a fact that a deadline had been imposed on you as well as on Mr. Erlichman to have a draft report by June 9?

A. The 9th, 10th, 13th, somewhere in there.

Q. Is that not extraordinary? Is that not extraordinary?

A. Well, I would say that timeframe was quite short, but I think that it has to be viewed in perspective, that frequently requests outside of the scope of our usual assessment process for information when generated from the Department level have deadlines that are short, and not necessarily always what I would like to operate within.

Policy relevant information sometimes is accompanied by a short turnaround time.

Q. Dr. Carter, there was no way for you to predict on April 10, or even on May 10, the amount of information that you would receive by the end of the comment period on June 10. Isn't that correct? And then for a deadline for the draft report, and I will use your date, 3 days later?

Q. Well, to be honest with you, at the time we put out the Federal Register notice, I had no idea how much information there was out there on this particular subject.

Q. But that's the point I am making.

How could a deadline for the report itself have been set for just 3 days after the end of the comment period?

Normally in these assessments, don't you take time after having received all the comments, to digest them and so on, don't you normally take more than 3 days to produce a report at the end of the comment period?

A. Well, yes. The assumption here was that we would be incorporating the information received as we received it, and through the end of the comment period continue to incorporate new, additional information, and I don't recall a time when we failed to incorporate new information that comes in to us before a report, the final report, has been transmitted anywhere.

Q. I understand.

A. So the assumption is always that we would incorporate all the information.

Q. For this assessment?

A. For this or any other assessment.

Q. Now, the standard operating procedure, is this the case in all past assessments? You have a comment period that ends on one date and then 3 days later you have to have the report?

Is that standard operating procedure? Because I fail to understand how you could do that, especially in light of the fact that you did receive a voluminous comment from Senator Heinz on June 9.

A. Oh. Well, obviously we—we spent two additional months incorporating that—much of that—information and other information we received into the report, so that, consistent with what I just said, that we would not fail to incorporate new information, irrespective of the deadline imposed.

So that's why we went 2 additional months, because——

Q. But, again, my question is——

A. The procedure is to continue to incorporate new input, new information.

Q. But again my question is to you, in other assesements, is it standard operating procedure to be told that you have to produce a draft report 3 days after the end of the comment period? Is that standard operating procedure?

A. No; not for the assessments we usually do for HCFA.

Q. Or for anyone else. Is that usual, or is that extraordinary?

A. It is not usual for us to receive an assessment from the Public Health Service.

We receive assessments from other agencies, and so in the conduct of those assessments are, our approach is the one that I mentioned earlier in terms of the timeframes involved, but we receive variable requests from the Public Health Service for information and, as I indicated, the turnaround time is usually short.

And, for instance, we received a request to review the National Heart Transplantation Study under very, very severe time constraints, which we accomplished, and I believe we did a thorough job of it. It was very taxing.

Q. Was there a Federal notice of public comment?

A. This was just a request for a review and comment. It was not an assessment as such.

Q. It was not. There was no solicitation for public comment, was there?

A. No.

Q. And so my question to you again is, in such a case as we are addressing now, this particular assessment, is it not extraordinary for a deadline for the report to be set 3 days, only 3 days, after the comment period ends? Is that not extraordinary?

A. Well, It's—we wouldn't—we don't usally do that.

Q. Therefore, is it not extraordinary?

A. I would say it is unusual, yes. I am not sure I know what you mean by extraordinary.

Q. Well, can you think of an example that fits this particular——

A. Out of the ordinary?

Q. In the past, can you think of one where you advertised for public comments and you were given only 3 days following the end of that public comment period to come up with a report?

A. No.

Q. So would you not agree, then, that it indeed is extraordinary, if not unique? Is it not?

A. Yes, sir.

Q. Did anyone at any time during the course of the assessment inform you that completing the assessment and the report as soon as possible was important to HCFA because that agency was preparing to publish a proposed regulation to reduce Medicare's dialysis reimbursement rates?

A. No, sir.

Q. Not at any time during the course of the assessment did anyone tell you that or give you that impression?

A. No.

Q. To your knowledge, did Dr. Marshall or Mr. Erlichman ever have any discussions during the course of the assessment with Mr. Rickard, that's Robert Rickard, or Ms. Anne Desmond in the PHS Executive Secretariat regarding the effect or impact of that assessment, of your assessment findings and conclusions might have on HCFA's proposed regulation?

A. No, to my knowledge, no. I have——

Q. To your knowledge?

A. No, I don't know that.

Q. Did Dr. Marshall or anyone else within OHTA and NCHSR, FDA, CDC, the PHS or from HCFA at any time during the course of the assessment make you aware that if the NCHSR assessment report concluded there were dangers associated with reuse, HCFA might have difficulty in going through with the reduction of the reimbursement rates?

Did anyone at all make you aware of that, that the NCHSR assessment report, that if it had concluded that there were dangers associated with reuse, HCFA might have difficulty?

A. No, I don't think so. I can't recall that ever happening.

Q. Did you have a discussion or discussions with Dr. Marshall on or about August 4, 1986, concerning the status and content of the assessment report?

A. August 4?

Q. On or about August 4.

A. I think so, yes. We did discuss completion of the report during that time.

Q. Did you at that time advise Dr. Marshall that the report was not finished and could not be completed to meet the August 6 deadline?

A. I believe I indicated that we could use more time to complete the report.

Q. To complete the report?

A. I don't recall specifically that we suggested it couldn't be made ready in fact—well, before the August 6 deadline.

I recall—I recall that we indicated—Mr. Erlichman had indicated to me, and I believe I had indicated to Dr. Marshall—that more time would be desirable to complete the report.

Q. Did you not inform Dr. Marshall that you felt very strongly that more time was needed to work on the report?

In light of ~~the~~ fact that you had just received on that day a fairly substantial number of documents provided to NCHSR by me with a cover letter dated August 2, and in addition to that I had informed Dr. Marshall in that letter, and you as well by telephone, that there would be a substantial amount of additional documents pertinent to your assessment that would be delivered to you as soon as we received it. Wasn't that the case?

A. Yes, I recall that. That's true.

Q. And in light of all that, did you not tell Dr. Marshall on or about August 4 that you felt very strongly that there indeed was a need to spend more time on the report in light of the fact that none of this material had been reviewed?

A. What day of the week was that?

Q. Do you have your calendar with you?

A. I have a——

Mr. Riseberg. Here, I have one.

Q. August 4, I think, was a Monday, if my memory serves me correctly. August 2 was Saturday.

Mr. Riseberg. I was a Monday.

A. Yes. I indicated around that time—I believe the preceding week I started indicating to Mr. Erlichman that we were going to have to—that we were at the point now where we were under the guns to complete the report, and so we have to wrap it up, and—but I think around the 4th we did discuss more time, and——

Q. In light of the new material that you had received and in light of the fact that we had informed you that you would receive additional material?

A. Yes, that's true, that's correct.

Q. As a matter of fact, I think in telephone conversations, did I not characterize to you the documents that we would be sending to you in a matter of days?

A. Yes, that's correct.

Q. And did you not feel at that time, based upon my characterization, that those documents to you, anyway, seemed to be pertinent and relevant?

A. The——

Q. Did you not express a desire to me for me to forward those documents to you?

A. Well, you indicated you had additional documents to submit, and we suggested that you go ahead and forward them.

We never refused to receive new information. I think that, in keeping with our tradition, we always accept all new information that is provided.

Q. And wasn't it on the morning of August 6 that I visited with you and with Dr. Marshall and later with Mr. Erlichman, and on that occasion I had with me a rather large stack of documents that I had just brought over from FDA?

These documents, none of which you had ever seen before, simply because they had not been provided to you, they related to establishment investigation reports by FDA concerning the very issues that your assessment was about. Isn't that correct?

A. Yes, sir.

Q. And didn't this at that time reinforce your belief, your concern, that the report would go forward without a substantial amount of information with regard to this issue?

A. Well, I must say that I was concerned, yes.

Q. And what was Dr. Marshall's response to your concern? What did he say to you on that afternoon just prior to the report being forwarded to Dr. Windom?

A. I don't remember specifically, other than to say that I know he had at that time indicated that he had prepared a transmittal, that the Department was expecting the report, and he and I discussed the transmittal memorandum that had been prepared, and the wording of it, and until we came to an agreement as to some of the wording in that transmittal memorandum to—to the Assistance Secretary.

Q. But in light of your having received or having been offered these many documents that indeed were pertinent to your assessment, were you not somewhat distressed on August 6 when that report was sent forward?

A. I don't know—I'm not agreeing to the characterization that you make my state of mind or attitude——

Q. Please, use your own characterization.

A. [Continuing.] Other than to say that—other than to say that I—I—I was regretful that we did not have more time to do what in my view would have been a more thorough job. I would have to say that much.

Q. Did you at the time understand why this report had to go forward without any question at all, had to go forward to Dr. Windom on August 6? Did you understand that?

A. No.

Q. Why didn't you understand it?

A. I don't recall. You know, I, see, I'm not always privileged to what the deliberations are in the—in the—in various parts of the Public Health Service or the Department.

Q. Hold on just a minute.

I'm sorry. I didn't mean to interrupt you, Dr. Carter. Go ahead.

A. Well, I believe that I didn't understand the June 2 deadline, either.

Q. Did you understand the July 10 deadline?

A. I didn't understand. I usually—I seldom understand many of the deadlines that I get, when I get a deadline, but I didn't understand either of the deadlines in this particular case, no, I didn't.

Q. Now, as you—as you sat or stood there in your office on the morning of August 6, and by that time knowing about the infection outbreaks in five different States, four or five different States, knowing that all of these reports had been sitting in the FDA, some of them for weeks, that they had not sent to you, realizing that you had a collection of documents that was provided on August 2 by this committee, realizing all of that on the morning of August 6, don't you feel that transmittal of that report should have been postponed?

Don't you thing there was a need at this time to postpone transmittal, and don't you think Dr. Windom would have understood why there was a need for that in light of all of this information that started pouring in?

Mr. RISEBERG. Have you spoken to Dr. Windom about this at all?

The WITNESS. I believe I attended a meeting——

Mr. MICHIE. I didn't ask him if he talked to Dr. Windom. Please let him answer the question.

A. I'm sorry. I am confused now as to what the question is.

Q. Let's go back again.

On the morning of——

A. Would Dr. Windom have understood?

Q. No. No. Let me repeat the question.

On the morning of August 6, you, having known by that time about all of this information, much of which you knew about, some of which you had, but didn't even have time to review, a lot of which you didn't yet have, but were going to obtain, not necessarily from FDA, but from this committee, didn't this give you cause to wonder why this report couldn't be postponed until all of that material involving death, serious injuries, malfunction, extremely poor procedures in reprocessing these devices and so on, didn't it give you cause to feel that this report should not be sent forward, that, instead, you be given more time to complete the assessment.

Wasn't that your feeling on the morning of August 6?

A. My feelings were that I wish I had more time, yes. I——

Q. Did you feel at that time that you felt that there was a need, that there was an essential need to postpone the forwarding of this report so that you could review that material and include it, or at least make a decision on whether or not to include it in that report?

A. Well, in the proceding days, and weeks—you see, I don't know, usually, what goes into setting some of the deadlines that are set, except to say that I was laboring under the impression that until—I was reading these memorandums—I was always under the impression that we were—we were preparing a report that would address the issues raised at the hearings on March 6, and identify additional areas, where appropriate, for further action by the Public Health Service.

I—I had no—you raised a question regarding HCFA, and I was totally unaware and do not know of any instance in which it was suggested to me that this was being done for HFCA. I mean, HFCA didn't ask for us to do it.

Q. That was not in my question.

I just wanted to know if, on the morning of August 6, you, having knowledge of all of these reports, stacks of documents that you didn't have from CDC, documents and reports pertaining to their findings and their inspections and their investigations, documents pertaining to FDA establishment inspections that go back all the way to 1984, these particular establishment inspection reports determining that there were serious GMP deficiencies by manufacturers of machines that are sold to automatically reprocess these devices.

Bearing all of that in mind, taking that all into consideration, did you not feel on the moring of August 6 that you indeed needed more time, and that if this was going to be a complete and thorough assessment that you needed to review all of that material, not only what you had in-house then, but what you were going to get 4 or 5 days later on August 11?

Didn't you have that feeling?

A. Sure.

Q. Did you express that feeling to Dr. Marshall?

A. Yes, sir.

Q. And what was his response?

A. I don't recall. I—I—I don't recall specifically what his response was other than to say that I understood at that time, from communication with him, that we had to go forward with the report.

I don't know specifically—I don't remember the specific details of that discussion other than that fact, and so it was clear to me that we had to wrap it up and move forward.

Q. I have here for your reference, Dr. Carter, a copy of Dr. Marshall's August 6 cover memo to Dr. Windom, under which Dr. Marshall transmitted the assessment report.

We also have here, and are going to share with you, a copy of the August 11 cover memo with Dr. Windom's signature, under which he transmitted this to Dr. William Roper, HCFA Administrator.

As you will note, both memos are only one page in length, but there are statements contained in Dr. Windom's memo to Dr. Roper that do not appear in Dr. Marshall's earlier memo to Dr. Windom.

For example, in the second paragraph of Dr. Windom's August 11 memo to Dr. Roper it is stated, "The findings to date indicate that when physicians and facilities exercise appropriate quality control over reprocessing of dialyzers," and I am going to skip a few words, and tell me if I take anything out of context, "patient outcomes appear to be no different in facilities that reuse dialyzers than for those facilities where single use is the normal operating mode."

Now, is this statement included in Dr. Marshall's August 6 cover memo to Dr. Windom? Can you find that statement anywhere in the August 6 memo, Dr. Carter?

A. No, sir.

Mr. MICHIE. Do you have a copy of the assessment report?

Mr. SCHULKE. Yes.

By Mr. MICHIE.

Q. We will now share with you a copy of the assessment report, the NCHSR Assessment Report, and I will ask you to turn to page 53, the first page, the beginning page, of findings and conclusions, and I will ask you if you can show us where this statement I just read can be found in the findings and conclusions of that report.

Do you find that statement anywhere in your findings and conclusions?

A. Which statement do you refer to?

Q. I am referring with the statement that begins, "The findings to date indicate that when physicians and facilities exercise appropriate qualify control over reprocessing dialyzers, patient outcomes appear to be no different in facilities that reuse dialyzers than for those facilities where single use is the normal operating mode."

I believe your findings and conclusions——

A. Thank you.

I—no, sir. I can't say that it appears, although I can see how someone could—could interpret the third sentence in the first paragraph of the findings and conclusions to suggest that this is what that particular statement implied.

Q. What statement is that?

A. The statement reads, "It appears that in a majority of these patients, no significant difference in complication rate has been observed. Yet, adequate studies have not been performed to assure that facilities choosing to reuse do so with optimal safety and clinical effectiveness.

It's possible for someone to——

Q. Would you have, would you have, if someone had asked you about this particular statement I just read, would you have put that in the August 11 memo? Is that statement——

A. No, I would not.

Q. Why would you not have?

A. I don't believe we know what the actual—well, we do not know what the actual rate of——

Q. Morbidity?

A. Morbidity——

Q. Or mortality?

A. Or mortality is.

Q. In fact, your report points out on page 26, and correct me if I am wrong, but your assessment report points out on page 26 that the data base maintained by CDC and based on their annual survey of dialysis clinics, has not been tested and hasn't been assessed, so therefore, there is no way to know whether the figures that they come up with are valid. Isn't that correct?

A. That's correct.

Q. And in addition to that, we find on page 28 a statement in your report indicasting that this survey, which of course solicits voluntary comment or reporting from these sentences or clinics. These clinics are not obliged to fill out the survey reports in the first place.

But on page 28, your report carefully states that there aren't even specific questions in their survey relating to increased incidence of infection. Isn't that correct?

A. That is correct.

Q. And so do you not find the statement to be contradictory to what your report states? This is not a true and accurate statement, is it, the statement that I read from the August 11 memo? It is a misleading statement, is it not, Dr. Carter?

A. I don't know that—whether or not—the statement was written with that intent.

Q. I didn't suggest that. I didn't suggest that at all. I am just asking you, on the face of it, is this not a misleading statement in light of what is contained in the assessment report?

A. Well, it would not be consistent with what the assessement report indicates.

Q. Referring you back now to the August 11 memo to Dr. Roper from Dr. Windom, it also contains a statement, "The absence of reported increases in the morbidity and mortality, given increased practices of reuse suggests that virtually all facilities are following adequate procedures."

Is this statement included in the August 6 memo to Dr. Windom? That is Dr. Marshall's August 6 memo to Dr. Windom.

A. No, sir.

Q. Can you show us where this statement is contained in the findings and conclusions of the assessment report itself?

A. No, sir.

Q. Are you certain it is not in there?

A. Yes, sir.

Q. Is this a true and accurate statement based upon the findings of your assessment, that virtually all facilities are following adequate procedures?

A. I think the phrase you just repeated is somewhat out of context. I think is a——

Q. Well, let's take the whole thing. In the absence of reporting——

A. A syllogism that might not be purely logical, but it's a nonsequitur, but——

Q. Is it a true and accurate statement based upon what you knew on August 11?

A. Some people argue that, there are people who argue, that the fact that reuse has increased from 15 percent in 1979 to some 60 percent at this time with a constant mortality rate observed, at least using the HCFA data base over the same interval——

Q. The HCFA data base?

A. Yes; HCFA, the Office of Research and Demonstration, maintains data on 95 percent of all dialysis recipients in the United States, and when we were interested in verifying what the true mortality rate is among dialysis recipients, because we saw 12 percent and 15 percent, I contacted Dr. Krakaeur, K-r-a-k-a-e-u-r, and Dr. Krakaeur showed me from data he presented and data I was already familiar with which he presented in Jerusalem when he and I participated in the symposium there last November, data suggesting that the mortality rate was 19 percent and that figure had not changed over the years.

Now, while there might be many explanations for those findings, some people argue that it is, it suggests that——

Q. That there is nothing to worry about?

A. That increased reuse does not bring with it increased adverse——

Q. But that isn't what this states, through, Dr. Carter. This states that——

A. That's why I said it is a nonsequitur.

Q. "Absence of recorded increases in the morbidity and mortality, given increased practice of reuse suggest that virtually all facilities are following adequate procedures."

Now, in light of what you know, what you knew on August 6, what you knew even in the month of July about what happened out there in the infection outbreaks, in light of what you have read in the reports from the FDA survey of dialysis clinics in California, the District of Columbia, et cetera, I will ask you again, is this a true and accurate statement?

A. I really don't know. I don't know if—I have no idea what kind of facilities are following what kind of procedures, and I have no idea——

Q. That's precisely what I am getting at.

A. What morbidity and mortality figures are in the facilities that reuse as opposed to those that don't.

So I would not know what the actual veracity of this statement would be, and I really don't know what the information—information source—utilized in formulating this conclusion would be, other than in my, to say in my view, I think the statement is really a nonsequitur, that from the one observation the other does not necessarily follow.

Q. Do you accept this statement?

A. No. I would not accept that as fact. I mean I wouldn't accept it as a fact because in my view we don't know that. We don't know anything about true morbidity and mortality, and we don't know——

Q. Understood. Understood. But isn't it a fact that you do know that this suggestion that virtually all facilities are following adequate procedures, isn't it the case that you do know that that is not so?

A. I know that all are not. I don't know what they mean by virtually all.

Q. Well, doesn't that mean to you that only a few may have problems?

A. I can't speculate as to what the author of this statement was trying to imply, other than when they say virtually all, it would suggest the vast majority. Yes. I just don't know, though, that that is true.

Q. As a matter of fact——

A. I don't know that.

Q. Can't you gather from the California report the many, many problems that were revealed in that survey, on process and procedure, just process and procedure alone in reuse, in reprocessing. And the D.C. report, similar, identical problems revealed.

In the five clinics investigated by the CBC, identical problems were processed and procedures all leading to injury, hospitalization and perhaps even one death of a patient down in Texas.

Knowing all of that, don't you think it is impossible for anyone to state at this time, or to suggest, that virtually all facilities are following adequate procedures?

A. Well, again, it goes to the "virtually." I don't know. When someone says virtually, it sort of covers the bases to the extent that it doesn't mean all, it doesn't mean 100 percent. Clearly it means less than 100 percent.

Q. Close to 100 percent, right?

A. How much less than 100 percent I can't quite, you know, quantify from a statement such as "virtually," but I can say that we know that if it said "all," then that would be incorrect based on what we know.

We do know that not all facilities are using adequate procedures, but we just don't know how many.

You know, it could be that the statement is correct. Maybe if we looked, we'd find out that 98 percent are. I don't know that. But I just have no way of knowing that at this time.

Q. If you had been consulted on this particular memo, would you have gone along with leaving this statement in here?

A. If this memo implies that we determined that, I wouldn't agree with that, no.

Q. Doesn't that—don't you take the meaning to be that?

A. What meaning?

Q. The meaning, the suggestion to Dr. Roper from Dr. Windom that virtually all facilities are following adequate procedures?

A. You mean do take that to mean that we determined that?

Q. No, no, no. I am asking you.

A. Or do I take that to mean that the memo intends to say that virtually all procedures are following——

Q. Well, it suggests, doesn't it? The word "suggests" is right there.

A. It is stating an inference based on premises that it explicity noted here and, you know, as I indicated, I don't believe that the premises are—I mean represent—a logical syllogism in the sense that the one follows from the other.

Q. And so if you—if you had been consulted by Dr. Windom, would you have advised him that this was not a good statement to put in that memo, that it was inappropriate, at the very least inappropriate, based upon what your assessment said?

A. Oh, I would have said that we didn't determine that.

Q. That's correct. Is that right?

A. We didn't.

Q. On or about August 8, the day after Dr. Marshall had forwarded the assessment report to Dr. Windom, a couple of days afterwards, did you have a discussion with Dr. Marshall regarding transmittal of the assessment report to HCFA?

A. Did I? Tell me again. You indicated when?

Q. On or about August 8, a couple of days after Dr. Marshall had forwarded the assessment report to Dr. Windom, did you have a discussion with Dr. Marshall regarding transmittal of the assessment report to HCFA?

A. Well, I wasn't party to that whole—I know that Dr. Marshall did have—yes, we had a discussion.

Q. You did?

A. I am trying to—I don't recall the specifics of it, but I know that we did have a discussion, yes.

Q. Were you not aware at that time that Dr. Marshall had drafted a cover memo for Dr. Windom's signature for transmittal of the assessment report to Dr. Roper?

A. I was made aware by Dr. Marshall that a transmittal was about to take place. I was not previously aware that we were going to transmit anything to HCFA, as I indicated earlier, but he had informed me to that effect, yes.

Q. On August 8, is that correct?

A. Thereabouts.

Q. And did he not share with you a copy of his first draft of that memo, and did you and he not discuss the contents of that memo?

A. Uh, yes.

Q. And did you not make suggestions on how the memo should be changed?

A. Yes.

Q. And what were your discussions, your suggestions, Dr. Carter?

A. Well, I felt, I think, I felt that this was not—I don't remember seeing it, this particular—I recall looking at a double-spaced draft to something, and indicating that that was not correct, or at least fully, I mean an accurate representation.

Mr. MICHIE. Why don't we take a 3-minute recess, if I may suggest, and go over the draft, and then we will pick up in about 3 minutes. Is that satisfactory with you?

The WITNESS. Fine.

[Recess taken.]

Mr. MICHIE. Now, we are back on the record.

By Mr. MICHIE.

Q. Getting back to what we were talking about, during your discussion with Dr. Marshall about this memo, did you not make suggestions on how to change it?

And I will ask you, before you answer that question, to read the first—I'll read the first sentence in the second paragraph of this draft, which Dr. Marshall purports to be his first draft of this memo:

> The findings indicate that when appropriate quality conrtrol is exercised over reprocessing of dialyzers and adequate disinfecting, washing and rinsing and related components is practiced, the risks to partients are no different in facilities that reuse dialyzers than for those facilities where single use is the normal operating mode.

Isn't that identical, virtually, I will use the word virtually unless you object to that, identical to one of the statements I read from the final memo?

A. Yes, sir.

Q. Did you take exception to that particular statement in your discussion with Dr. Marshall?

A. Yes.

Q. And what was his response?

A. I don't recall. I do know that the memo, he was going to discuss it with other parties whom I don't know who they are or were, but—but—but——

Q. You did take exception with that statement, though, did you not?

A. I—yes.

Q. Why did you take exception with that statement?

A. Because——

Q. Do you recall?

A. Yes; because we didn't know.

Well, there were two things that were foremost in my mind. One is, we didn't—we don't—know what the specific quantifiable risks are for reusers as opposed to non-reusers. That was my first reason.

And the second reason was that in the one study that had actual quantified data that I looked at on the specific complication rate, which was the D.C. study, it was only in the facilities that practiced reuse that there were complications, and so—but I had no idea whether or not, I mean, if you looked more broadly, how much more of that kind of findings would be—would be noted.

Q. At that point, you had not read the California report, had you?

A. At this point?

Q. You didn't have it at that point?

A. I didn't have the California report, no.

Q. So you had no idea what was in that report?

A. No.

Q. I will direct you now to the last sentence of the last paragraph of that draft memo, and it states:

> The absence of evidence of increases in the morbidity and mortality given increased parctice of reuse shows that facilities are following appropriate procedures except in a very small number of instances.

Now, is that not almost identical to the statement, the second statement, that I read to you from the final August 11 memo to Dr. Roper?

A. There are some similarities, yes.

Q. Would you—would you agree that the one change that was made was that instead of using the phrase "in a very small number of instances" the final memo said "in virtually all?" Is that what you read there?

A. Yes. Yes, sir.

Q. Did you take exception with the statement made that I just read to you from that draft memo in your discussions with Dr. Marshall?

A. Yes. I—again for the same reason. I know that we don't know. I think that, you know, in all fairness, I think that Dr. Marshall, as many other people, perhaps feel that the absence of visible evidence of complications being reported suggests that this is the case, this is true.

I don't know that. I take a little different view in my own mind simply because I need to see data, hard data, that is systematically gathered on that position. That is why——

Q. You didn't share it?

A. Yes. I didn't share it.

Q. You took exception to that?

A. Well, I just don't know that we know there's—that, you know, any large risk, or small.

Q. Wasn't your advice to him say—not to put that statement in the memo?

A. Well, my advice, I believe, was that the memorandum you just showed us, showed me here, the August 6 memorandum.

Q. The final version?

A. The transmittal memorandum to Dr. Windom.

Q. From Dr. Marshall?

A. Right, that I felt this memorandum states in a manner that is more acceptable to me the—what would be closer to what we determined.

Q. So, effective during that discussion, you were comparing with him the content of his August 6 transmittal memo to Dr. Windom with this draft, Is that not correct?

A. Yes.

Q. And is it not a fact that you did take exception to both of these statements in light of the fact that neither statement appears in the August 6 memo?

A. You know, I think so. To be honest with you, I haven't looked at this for—since that time—and I am just trying to recall here what all the specific statements were that we discussed, and I can say simply that there was exception taken and that the reasons for the exceptions were what I indicated earlier.

Q. I understand.

A. That Dr. Marshall indicated to me that it really would not be ultimately up to him what the final shape of this memorandum is, but I did not know that it was really—would have been, or was going to be—transmitted at the time. I mean, at the time. I thought that this was a proposed matter under discussion. I didn't know.

Q. During the discussion that you had with Dr. Marshall about this draft memo, didn't he finally agree to make some changes based upon your exceptions?

A. Which memo?

Q. The draft memo on the day that you discussed the draft memo with him, the one we have just gone over, did he agree to make some changes in order to bring the memo back in line with what was stated in the August 6 memo?

A. I don't know that.

I think that what was indicated then was that it has to be discussed with other people, and I didn't—I didn't know who all the other people were, but I knew that, that—he left me with the impression that what finally emerged here was not going to be up to him, so that—

Q. It was out of his hands, is that correct?

A. I think that's what he indicated, yes.

Q. Did he indicate that someone had indicated to him from some other quarter on what should go in this draft memo?

A. I don't remember that.

I left with the impression that other agencies were going to participate in formulating the final memorandum, so that I knew that—I knew that that happens, and that that was not—that was a reasonable statement. I mean, to assume that other agencies and other people were going to make sure it is consistent with what the Public Health Service as such would say.

Q. But in light of the fact that you as Director of OHTA—I'm sorry. What did you say?

A. I just added "consistent with what would be the PHS position."

Q. Consistent with PHS position?

A. Yes.

Q. In light of the fact that you yourself, along with Mr. Erlichman, has conducted this assessment, that you yourself had personally reviewed the report, that you yourself knew that in that report was information clearly indicated that the data base at CDC certainly could not be used to reflect these two statements, didn't you feel that at that point you should indeed have had input in regards to what was included in the memo that was to be sent to Dr. Roper?

A. I don't recall that I felt that way. All I know is that I expressed my thinking about it, and——

Q. But isn't it reasonable that you would have had input, because doesn't this memo purport to reflect the findings of your report?

A. Not necessarily. I put, I——

The REPORTER. Excuse me just a minute.

[Pause.]

By Mr. MICHIE.

Q. Doesn't this August 11 memo, Dr. Carter, purport to reflect in a summary way the findings of your technology assessment?

A. It seems to do so; yes.

Q. Did Dr. Marshall state to you at any time during that week on up to August 8 that his intention in drafting the memo that went from Dr. Windom on August 11 to Dr. Roper was to assist or help out HCFA, or in words to that effect?

Did he state that to you in any discussion during the week of August 3 through August 8? At any time?

A. Somewhere in that week, in that——

Q. In that week.

A. He may have. At that time, I—I—I—I was—I don't know. I—I—he may have done so.

All I can say is that during that time I know he had brought this draft memo to my attention indicating then that there was some consideration being given to providing it to HCFA, but I don't—I don't recall the specific statement that, you know. I mean it's entirely possible that that statement was made.

Let me see if I can think back to what context it would have been made in.

Q. Let met try and help jog your memory.

Were you not aware by August 8 that HCFA was going to publish its final regulation on August 15, or very soon in the very near future, that it would reduce the rates for reimbursement in dialysis?

A. Yes.

Q. Were you not aware of that?

A. Yes.

Q. And was Dr. Marshall not aware of that?

A. I assume so. I don't know. I mean I don't know specifically what he was aware of, at what time, and in what terms of those things, but I think he was generally aware of that; yes.

Q. Are you aware, to your knowledge, are you aware of this memo having been transmitted to HCFA by the Public Health Service in order that HCFA would have your assessment report prior to publication of that regulation?

A. I did not know that it was being transmitted because after around the time you stated, where Dr. Marshall and I had this discussion, I heard no more about it until perhaps the middle of August, around the 15th or shortly thereafter. I think it was on the 15th that I received a copy of this memorandum.

So I didn't know, I didn't know prior to that time that anything had been finalized, or went anywhere.

Q. I understand. In other words, you lost track of the memo after that discussion with Dr. Marshall?

A. Yes; that's right.

Q. And do I understand, then, that what you are saying is that after that discussion, he no longer, he didn't at any time thereafter come back to you and discuss the memo again——

A. Well, I didn't know.

Q. [Continuing.] Prior to August 11?

A. That's right, I would say. Yes; that's correct.

Q. Did he at any time inform you or give you the impression that this memo was being drafted for the purpose of sending the report to HCFA, simply because HCFA was going to publish its regulation, and if HCFA was going to justify publication of its regulation, it should indeed have a copy of your report as it relies upon your reports and other assessments in making determinations and decisions with regard to administration of its activities.

A. What is the question?

Q. The question is, did Dr. Marshall make you aware, or give you the impression in discussions during that week, any time during that week of August 3 through August 8, that the report was going to be sent to HCFA?

A. Yes.

Q. Prior——

A. Well, he indicated that that was being—that was being considered at that time.

Q. Being considered?

A. Some time shortly after we sent the report to the ASH, it was being considered for transmittal to HCFA, and that was made—brought to my attention—in connection with this draft memorandum.

But, again, I didn't know. All I knew was that it was being considered. I didn't know much beyond that, or even whether or not it had been transmitted.

Q. But did you get the impression from your discussions with Dr. Marshall that he felt that HCFA should have the report before they published the regulation, because the report surely would have impacted upon HCFA's decision to publish.

Did he relate that to you, or give you that impression during any of your discussions with him that week?

A. I think that around the time that this memo was being—I am just trying to recall back now, and by partly speculating here.

I think that around the time this memorandum was, I looked at the draft memo, he did indicate that it was being considered for transmittal to HCFA.

What I am trying to recall is whether or not he at that time indicated to me it would somehow affect those regs, or whether I just thought so, or made that connection in my mind, because in truth I did not connect these two efforts.

I thought one thing was going one way and another, another and for a while I felt, as HCFA does frequently, we are doing assessments for the Bureau of Coverage Policy, and their Bureau of Reimbursement Policy is doing something else at PROPAC, setting up—setting up DRG weights and calibrating them for things that we are going to recommend not be covered.

Q. But in this——

A. So I felt the left hand and the right hand were probably doing their usual asynchronous movements.

Q. But in this case, though, we were talking about an assessment that had a direct bearing, was extremely relevant, was it not, to take this decision to publish this regulation, the regulation to reduce rates?

Didn't it have a direct bearing on that? Should not HCFA have considered the assessment report prior to publishing it?

Would it not have been illogical for HCFA to publish prior to your report having been forwarded to them?

A. Well, I must say that it wouldn't be without precedent, in terms of HCFA decisionmaking about matters that were even under assessment, so that I would not have viewed that as even unusual.

I know things that have been pending in our office that action has gone forward on, so that it would—it clearly did not, would not have struck me as being totally, although that's not the way I believe we do things or should do, it wouldn't have been without precedent, or even highly unusual that sometimes HCFA proceeds to—proceeds to make decisions and——

I don't fully claim to understand how HCFA works in terms of their internal machinations, so that——

Q. But in light of the fact this particular issue is highly charged, there was very, very intense interest in this particular issue, not only by this committee, but by the FDA, and wasn't it your understanding that HCFA had an interest in this assessment? Wasn't that your understanding?

A. I know that some time after around the 8th of August, I—the conclusion resided in my mind that once transmitted to HCFA that it would affect, but I don't recall whether or not I was told that, or whether or not I made that connection in my mind.

I don't—that's what I'm trying to—we proceeded, in my mind, we disassociated this assessment from the other activities from the beginning, because—first of all, it was not referred to us by HCFA, and secondly I felt that the Department was going to respond to a promise made to Senator Heinz and the committee at the time of the hearings to evaluate further action where appropriate by the Public Health Service.

And so I felt all along that we were doing that, and no one ever indicated to me until the time I was made aware of this draft that something like we transmitted to HCFA, that that would even occur.

As a matter of fact, Marty Erlichman and I sat down from time to time, and said, "Gee, this is an unusual one." We have had phone calls asking, "Who asked you to do the assessment?" And so forth, and so we thought, hmm, this is unusual.

Q. But regardless of whether or not HCFA asked you to do the assessment, does it not stand to reason that if they were going to publish a regulation that would impact directly upon the frequency of reuse—do you disagree with that statement? Does not the reduction of the rates encourage increased reuse? Does it not?

A. Well, I think that dialysis centers, and we included in our report a statement to the effect that most facilities admit that their primary motive for reuse is economic, but we have also observed the difference between proprietary and nonproprietary facilities, in that the nonproprietary tend not to reuse and the proprietary tend to reuse.

We also notice that hospital-based facilities tend not to reuse.

Q. My question, again to you, and please answer the question yes or no: Would you not agree that reduction of the reimbursement rates for dialysis would encourage increased reuse?

A. That's a conclusion that, again, for the same reason that I——

Q. No; it's a question.

A. Oh.

Q. It's a question.

Would it not, does it not, follow that if you reduce the amount of compensation for a dialysis session that it does in fact encourage reuse?

A. Would I conclude that? I wouldn't conclude that in the absence of data.

Q. I am not asking you to conclude it. I am asking what would the clinics do?

A. What would they do?

Q. Right.

A. Well, see, again, for the same reasons that I, and I want to be clear on this point, that I disagree with other statements that are made in some of the documents you have shown me today.

I would have to say I can't say that, either, because as a purist when it comes to conclusion forming, I would want to see a cause-effect relationship established, a causal one, that could be demonstrated based on evidence.

I mean, if I went around and asked 20 percent of the 1,400 facilities in the United States in some systematic survey why they moved to reuse and they told me because somebody dropped the rate, I would take that to be a statement from those facilities that had significant, ah, meaning, and I would form conclusions on that basis.

Q. Are you——

A. I could infer that it might, but that is only speculation.

Q. Well, what do you think? Do you think it would encourage reuse?

A. Well, it depends. If you are a small facility, where there are no economies of scale in reprocessing and reusing, you may just end up losing money. It still might not be profitable to reuse.

Q. Suppose you were a large facility?

A. Well, they have indicated repeatedly that, that—and it's published in the literature—that their primary incentive is to reuse, and that there are economies of scale associated with their largesse and efficiency of their processing, and——

Q. You are aware of the fact that in 1983 there was a reduction in the reimbursement rate, aren't you?

A. Yes.

Q. What's happened since 1983 as far as the incidence of reuse is concerned? Has it increased, gone down, or stayed the same?

A. It has continued—it has increased since 1978.

Q. No. I am asking you since 1983. Has it increased, has it stayed the same, or has it gone down since 1983?

A. Reuse has increased progressively since the late 1970's.

Q. But, since 1983, has it not also increased considerably more than it did in previous years?

A. But, you see, I don't know that the slope, the rate of increase, is greater since 1983 than the period between 1979 and 1983.

Q. Do you know that there was an increase?

A. I know that there was an increase. I know that the rate—I don't know what the relative slopes of the curves are. I am just saying that it could have been a trend that started that just kept catching on and on and on over the years, and so——

Q. But I though you said a moment ago that the whole question of reuse is primarily centered on economic considerations.

A. Well, I said that some have indicated that that was their motive. I didn't——

Q. Don't you state so in your report, that that is a very strong reason for increasing reuse?

A. I believe that the facilities, that some facilities claim that that is the case. I didn't——

Q. Do you disbelieve them?

A. I do—I neither—I can tell you this much. To the extent that they indicate that, I would have to say that that's the statement from whatever number of facilities indicate that, but, you see, I don't know how many facilities were surveyed for those conclusions.

Maybe when we check, we could find out that's 10 percent; maybe that's 80 percent.

Q. But let me——

A. But I don't know the number with that specificity.

Q. Let me put the question to you this way, Dr. Carter: Do you think that there is a potential for the rate reductions that go into effect on October 1 to encourage increased reuse? Do you think there is potential for that?

A. You mean if that is possible, that——

Q. No. I asked you if you think there is potential for that rate reduction to cause increased reuse?

A. Well, there is a potential for almost anything.

Q. Please. If you would, answer the question yes or no.

Do you believe that there is a potential for the rate reductions to encourage increased reuse? Yes or no.

A. You see, I would be speculating if I said that I believe that potential existed, because I have personally not, and we have not, derived any primary information on the economic issues pertaining to reuse.

Our information on that is purely secondary, and for the same reasons that I would be critical of conclusions that are based on defective information about the morbidity and mortality, I would have to be critical, I would be consistent and be critical about the conclusions about the economic issues.

Q. But I am not asking you for a conclusion, Dr. Carter.

A. There are indications, there are indications that there is a relationship between rates and reuse.

Those indications are not formulated based on—I do know that there are relationships along the lines that I described earlier, proprietary, nonproprietary, hospital based, nonhospital based, large, small, in that the first sets of groups would reuse more than the second set. Hospital based—I'm sorry—outpatient versus hospital, proprietary versus nonproprietary, large versus small, would reuse in that relationship especially.

But I don't know that we have data to show that, I mean, why people——

Q. All right, let me put the question to you again, and let me qualify it first.

A. I know that they don't have the data.

Q. Do you think there is a potential for these rate reductions to encourage some of the dialysis clinics to increase reuse?

A. Well, some facilities have written in to tell us that the—that if the rates go down, they are going to have to do this, or there are organizations that have written in indicating to us that if the rates are—NAPHT, for example—indicated that if rates are reduced——

Q. That it is going to do what?

A. That it will encourage more reuse on the part of centers not currently reusing. Many facilities admitted to that relationship.

We met with several organizations, now, who indicated according, also, so that——

Q. In light of what you just stated, the fact that a number of individuals, organizations, or groups have indeed written you, discussed with you this potential for causing increased reuse, should not have HCFA relied upon the results of your assessment to determine whether it should have gone forward with its final regulation?

A. If they assume that rate reductions generate reuse, and if they further assume that reuse is dangerous, then I would say that maybe so, they probably should.

You know, I like to believe that what we do is meaningful, and as we look at it by users and information for making decisions.

Q. Now, if HCFA had no interest whatsoever, and if they expressed no interest whatsoever to you or anyone connected with this assessment, why, then, did Dr. Windom find it necessary to transmit that report to Dr. Roper 5 days before publication of that regulation? Do you know why?

A. No. I don't—you see, I don't—I can't speak for the—for the sub-Cabinet-level members of the Department.

I am certainly not in that league, or am privileged to the deliberations in those areas of the Department, and so——

Q. Fine. I understand.

Now, if—if—the purpose of transmitting that report to HCFA was so that HCFA could consider your findings in making a final decision on publication, do you think 4 days was time enough for HCFA to analyze, to digest, to consider your findings?

A. No. I don't know whether—what HCFA's deliberative process entails.

Some agencies may very well look at the bottomline recommendations, particularly if they don't view themselves as having the expertise residing within their organization to analyze the findings of the Public Health Service, or at least any statement of findings from the Public Health Service. So they may not consider themselves to be—to be—to have the appropriate expertise to even analyze the information.

Q. Did anyone at HCFA, or anyone associated with HCFA, phone you, telephone you, any time prior to August 15 to ask you any questions at all about your findings?

A. I spoke to Cathy Butto on one occasion, but it had to do with something else. It wasn't——

Q. Not related?

A. But the question at the end of the conversation was, "Oh, by the way, where are you guys with your reuse?"

Q. When was this?

A. I don't—it was probably in July.

Q. But I am talking about in the immediate weeks, the 2 weeks prior to August 15.

Did you or to your knowledge did anyone in your shop, in your office, receive any calls at all from anyone at HCFA asking you to explain, asking you to summarize, asking you for your advice and counsel on the findings and results of your assessment?

Did anyone do that from HCFA?

A. Not that I know of. You see, we don't—my staff, I mean, if they called my staff, I wouldn't necessarily know, because we don't screen the calls for staff, and I don't know.

Q. You don't know?

A. I remember once or twice I spoke to someone. I specifically remember speaking to Cathy Butto about liver transplants.

Q. Well, but this has nothing to do with liver transplants.

A. No, I know, but at the end of the conversation, she mentioned to me, "How are you all doing with your"—that was almost a quote—"How are you all doing with your assessment of reuse?"

Q. That was in July?

A. That was in July.

Q. Did she ask you for specifics about your findings?

A. No.

Q. Let me share with you a copy of the final regulation announcing the reimbursement rate reduction. Were you or anyone on your staff given the opportunity to review this regulation prior to publication?

A. No.

Q. Are you aware that HCFA's published regulation contains statements pertaining to the safety and efficacy of reprocessing and reuse of disposable dialysis devices? Are you aware of that?

A. No.

Q. For example, if you will turn to page 16 of that regulation near the top of the page, it states, "The absence of a demonstrated need for a particular method of operation to ensure patient's safety, medical practitioners should be permitted to devise appropriate methods of treatment."

Do you see that statement, doctor?

A. Um hum.

Q. Is this an observation or finding or conclusion in the NCHSR's assessment, to your knowledge?

A. No.

Q. Do you agree with this statement?

Mr. Riseberg. Have you ever seen that statement before?

Mr. Michie. He just said he had.

Mr. Riseberg. He has just been given it. It is—how long is this document?

Mr. Michie. Take your time. Take your time, Dr. Carter.

Mr. Riseberg. This document is 34 pages and it has just been placed in from of him.

By Mr. Michie.

Q. Take your time, Dr. Carter, and tell me if that statement—if you will, examine the statement, where it is on the page, and tell me if it has been taken out of context, please. And I will ask you once again—pardon?

A. I—I—you know, again, I may be a little critical about the way things are worded, but I know what it is saying.

It basically says that medical practitioners should make their own decisions about appropriate treatment. In other words, the practice of medicine should make its own clinical decisions.

But I don't know what "in the absence of a demonstrated need for a particular method of operation to ensure patient safety" means.

I don't know whether they are saying one is absent and therefore practitioners should decide, or that there is no demonstrated need for that. I don't know what it's saying.

Q. Well, this document is about rate reductions in dialysis, isn't it?

A. Sure.

Q. So would you imagine they would be talking about something else there?

A. Well, this statement, I am taking it out of context, too, and——

Q. Well, please read, if you want to, read a sentence before it, the sentence after it. If you think it is taken out of context, please do so.

A. I would rather not comment on this, because I, believe me, I haven't even—I haven't seen this whole thing. I didn't read the Federal Register publication on August 15 on this subject, and I didn't—I didn't look at this before being——

Mr. Michie. We will take a recess for 3 minutes.

[Recess taken.]

Mr. Michie. Back on the record.

By Mr. Michie.

Q. Dr. Carter, I am going to take the time to read to you——

A. Can I make a comment first for the record before we proceed?

Q. Please.

A. I would like to draw one distinction between two functions that HCFA performed in relation to what we do for purposes of clarification.

In the Health Care Financing Administration, there are coverage decisions and there are reimbursement decisions, and while coverage is a subset of the reimbursement concept, they are quite different and, in enabling coverage decisions, it is a matter of deciding what should be paid for under Medicare.

The reimbursement decisions are how to pay for—for what you decide to pay for.

Q. Um hum.

A. Now, our relationship to HCFA primarily assists them in deciding what they should pay for. We do not get involved in decisions about how they pay for what they decide to pay for.

And so, while sometimes they seek cost effectiveness information from us, it is not a priority of ours to provide that kind of information.

And so it is not at all to be viewed as unusual that we would really disassociate ourselves from a reimbursement decision, like how they are going to pay for ESRD treatment, you see.

Q. I understand.

A. So that, with that point, I would like us to bear that in mind as a conceptual framework as we proceed in this.

Q. Fine, understood. Thank you, Dr. Carter.

I am going to read to you from, beginning on page 15, the entire section that includes that particular quote that I read to you a moment ago. This is a comment.

[Discussion off the record.]

Mr. MICHIE. On the record.

By Mr. MICHIE.

Q. I'm reading now from a comment, one of the many comments that's included in this final regulation. On page 15,

> Comment: Various commenters discussed the interrelation of economy and efficiency and quality of care. They stated their concerns, including that certain cost-cutting measures might impinge on quality of care, use of fewer and less qualified staff, increased reuse of supplies, poorer techniques for reuse and facilities inappropriately placing patients on home dialysis.
>
> Response: This is HCFA's response.
>
> The conditions of participation for ESRD facilities (42 CFR subpart U) establish the requirements that we believe are necessary to ensure quality care. Nothing in the composite rate system allows facilities to depart from these requirements. Facilities are surveyed periodically to ensure that they continue to be in compliance with these requirements.
>
> The medical community does not agree on any one model for the dialysis procedure. There is a wide variation among the staff complements and practices at various facilities. In the random sample of facilities that were audited, we included facilities of all types. In the absence of a demonstrated need for a particular method of operation to ensure patient safety, medical practitioners should be permitted to devise appropriate methods of treatment. We will continue to monitor the program to ensure that quality standards are maintained.
>
> Concerning the assumption that the lower rates will force facilities to inappropriately place patients on home dialysis, we have no evidence that patients are forced on home dialysis where it is inappropriate. We do not believe that facilities will perceive such a strategy as cost effective, since patients who are unsuitable for home dialysis are expensive in terms of support services that must be furnished by the facility, including back-up dialysis in the facility. Any increased hospitalizations for the patients would also reduce the facility's revenue. Whether a patient dialyzes at home is a decision for the medical professionals and the patient to make. For these reasons, we do not believe facilities will inappropriately place patients on home dialysis. The statute requires us to promote home dialysis through the payment system.

That ends that particular response to HCFA, to the comments that began on page 15.

Now, to get back to my question, and that was the statement:

> In the absence of a demonstrated need for a particular method of operation to ensure patient safety, medical practitioners should be permitted to devise appropriate methods of treatment.

My question to you is, did HCFA consult with you or anyone on your staff pertaining to this particular statement with regard to ensuring patient safety?

A. No.

Q. Does your assessment report address the issues of safety in reuse of dialysis devices?

A. Safety and——

Q. Safety and efficacy and cost effectiveness of hemodialysis reuse?

A. Yes.

Q. Do you agree with that statement that I just read that HCFA made in its final regulation?

A. Well, agree with it or not, I haven't had enough time to evaluate the statement, but I want to comment briefly on one point that it says here.

Q. Please do.

A. And this is for reasons other than our assessment. Home dialysis was not a feature of our assessment.

Q. We understand.

A. Some 15, 16, 17 years ago when I was at the University of Washington, Dr. Scribner, a well-known pioneer of hemodialysis in this country, who taught me nephrology and with whom I had the opportunity to participate in the dialyzing of patients, maintained that it was desirable to have as many patients who could be on home dialysis as possible, and in Seattle at that time, we were the only place in the United States——

Q. Dr. Carter if I could interrupt you for a minute. This question does not address home dialysis. What we're talking about is reuse.

A. I thought what we read there——

Q. The comments picks up on home dialysis. It leaves the reuse issue and talks to home dialysis.

A. I thought we were focusing on the whole comment.

Q. Not at all. We are focusing on the first part that deals with patient safety and reuse.

My question to you is in light of HCFA's attempt in its own final regulation, to address patient safety, should not have HCFA consulted you insofar as addressing this particular question?

A. My view is that these agencies, we do not have oversight responsibilities over HCFA, and they are not really obligated to consult us on any——

Q. I did not ask you that, Dr. Carter. I asked you in light of the fact that HCFA did attempt to address patient safety on this issue, the very issue that you addressed over a period of 3 or 4 months, should not HCFA have consulted with your office in making such a statement?

A. I wish not to comment on what HCFA should or should not do, because I believe it would be inappropriate for us to start attempting to define how other agencies' policies are to be formulated.

Q. But, Dr. Carter, you just got through——

A. I assume they had consultants. I don't know that. I know they consult us on their coverage policy development, and I don't know what they do most of the time on reimbursement policy.

Q. Is that statement concerning patient safety, is there a statement anywhere in your assessment report that resembles that statement, to your knowledge, in the findings and conclusions, or anywhere else?

A. That says that—I'm sorry. What page are we on now?

Q. We are talking about the statement I read, in the absence of a demonstrated need for a particular method of operation to ensure patient safety.

A. I see what you mean.

Q. Is that statement anywhere in your findings and conclusions?

A. No.

Q. If someone were to ask you, if someone were to have asked you to include that in your findings and conclusions, would you have? Is that an appropriate statement for your assessment report?

A. Our assessment report in the findings and conclusions says something that is somewhat opposite to this.

It talks about the need for uniform standards, not standards that are made by individual practitioners. We talk about uniformity of standards to assure quality and safety and efficacy.

Q. Would you say, then, that obviously HCFA did not get the statement, or anything resembling it, out of your report or by word of mouth from your staff?

A. That is a fair—well, I don't know if my staff talked to them, but I can say that they didn't get it from my report, or from me.

Q. Do you think Mr. Erlichman would have transmitted this statement to HCFA?

A. I cannot speculate on what Mr. Erlichman would or would not do, but to my knowledge they have not spoken to him about this. I am unaware of it if they have.

Q. How do you imagine HCFA came to conclude this?

A. I have no idea.

Q. Certainly not with the assistance of your office, is that correct?

A. That is a correct statement.

Q. And if HCFA were to have come to you prior to publication of their final regulation, what would your advice have been to them?

Because after all, this is your role, your role, to advise HCFA in these matters. So what would your advice been, if Ms. Butto, or somebody at HCFA, would have come to you and said, "Dr. Carter, how do you feel about this statement? Should we leave it in here, or chage it?" What would your response have been?

A. Well, I would say this: I don't really want to comment on what my response to this would be in that I really have not looked at this whole document in terms of—I haven't looked at the regs, and I can, to the extent that I would imagine that I would have comments on the whole set of regs, but I don't know what those comments would be, because I really haven't looked at them, but——

Q. Nonetheless, you don't agree with that statement, isn't that correct?

A. Well, it should not be consistent with what our report says.

Q. And so, therefore, you don't agree with it. Isn't that right?

A. It wouldn't be something that we would have—that we—let me rephrase that to say that this is not what we presented in our findings and conclusions.

Q. In fact, it's the opposite, isn't it?

A. It would be in conflict with what our findings—our conclusions—stated.

Q. Do you recall having visited this committee's office on April 17, 1986, along with Mr. Erlichman and another OHTA staff member?

A. Some time between March and April, yes.

Q. What was the purpose of your visit?

A. I believe we were invited to look at, among other things, the Deane report, and the materials that the committee had available that following the March 6 testimony it thought should be shared with those who are doing the assessment.

Q. Did the three of you meet with the committee's staff concerning the committee's investigative findings on dialyzer reuse?

A. Yes.

Q. With whom did you meet, if you recall?

A. I believe we met with you, Mr. Michie, and I believe Mr. Cunningham, and I think that was all.

Q. Were you given the opportunity to review documents pertaining to the investigation, the committee's investigation?

A. Yes, sir.

Q. And did you do so?

A. Yes, sir.

Q. What did you learn from your visit to this committee office?

A. Well, I learned the first, most important thing, I feel, is that the substantive basis for certain conclusions in the NIH report, National Kidney Foundation, 1981–82 final report, entitled "Multiple Use of Hemodialyzers," was lacking in substantive factual data to support some very important conclusions.

Q. On which there is widespread reliance.

A. Insofar as reuse is concerned?

Q. Yes, sir.

Q. Had you known about this controversy prior to the March 6 hearing?

A. The controversy——

Q. The controversy surrounding this report that was revealed to you in detail here. Did you know about that?

A. Yes. I became aware of some controversy in reviewing materials in preparation of testimony, but I did not have the full scope of information surrounding that controversy.

Q. What did you know at that time, do you remember?

A. At that time, I was made aware from documents I received from the National Institutes of Health that Arthur D. Little took exception to the findings and conclusions of the Deane report of the Multiple Use of Hemodialyzers Report, which I refer to as the Deane report.

Q. And that's all you knew at that time?

A. I knew that there were several detailed matters involving——

Q. This is prior to the hearing. I want to make that clear.

A. Yes. And—and that the Deane report was remanded for revision following its original November 1981 publication date and well—released in February 1982 the final report.

Q. Right. Was the first report not dated June 1981?

A. I could be off by months. Yes, it was somewhere in the second half or the middle of 1981.

Q. The reason why I ask you that is because on August 9, 1981, and we are going to provide you with a copy of that letter, a letter dated at the time October 9, 1981, to Dr. Norman Deane, principal author of Multiple Use of Hemodialyzers. This is a letter from Dr. John Ketteringham of Arthur D. Little, Inc., ADL. Wasn't this one of the documents we shared with you——

A. Yes.

Q. Had you seen this letter prior to your coming here on your visit, whether it might have been in late March or April? Had you seen it prior to coming here?

A. I saw the letter, but I did not see the attachments.

Q. You had seen the letter?

A. I had seen the letter by Arthur D. Little. Let me just look back and see if this is the one.

Q. You do not recall being surprised?

A. I was surprised by some of the detailed information that surrounded this that I was unaware of prior to the visit here.

Q. So what you are saying, then, is that when you came here you did not register surprise at even the existence of that letter?

A. I am trying to recall here.

I saw a letter by Arthur D. Little prior to the testimony that took exception to the Deane report's findings and conclusions, to its conclusions, and some of the findings, and the way, the manner, in which they were represented.

I did not know what the details of those exceptions were until I came here.

Q. So what you are saying, then, is that you saw the letter. You are certain that you saw that letter, not the attachments, but are you saying you are certain you saw that letter prior to the hearing of March 6?

A. My recollection serves me that this letter was a part of the materials provided to us by NIH in the briefing.

Q. In the briefing?

A. In the planning for the March 6 testimony.

Q. It was?

A. Yes.

Q. But was the attachment along with the letter?

A. No.

Q. It was not?

A. It was not.

Q. You are aware that ADL was the subcontractor on the Multiple Use of Hemodialyzers Report and performed much, if not most, of the research for that report, aren't you?

A. Yes, sir.

Q. By the way, have you, or to your knowledge has anyone else at NCHSR, read the February 1981 ADL report, "The In Vitro

Evaluation of Certain Users Relating to the Multiple Use of Hemodialyzers"?

A. Could you refresh my recollection as to the subject report?

Q. Do we have a copy?

A. I did read a report that contained information along the lines you described.

Q. You did?

A. Yes.

Q. When did you——

A. Yes. Whether or not it is the report you are speaking of, I would have to refresh my memory.

Q. Do you know whether or not Arthur D. Little did more than one report on this issue?

A. To my knowledge, no, I don't know. I don't know that he did more—that he did not do more than one report.

Q. All right.

Getting back to the October 9 ADL letter, 1981, isn't this letter sharply critical of Dr. Deane's report to the extent that ADL charges Dr. Deane with misrepresenting and malinterpreting——

A. Yes, sir.

Q. The data?

A. Yes.

Q. As a matter of fact, the ADL letter points out that Dr. Deane did not even give that firm the opportunity to review Dr. Deane's report prior to publication. Isn't that the case? Doesn't that letter say that? The letter is right in front of you, sir.

A. That's what it says.

Q. To your knowledge, has Dr. Deane or the NIH funder of the Deane report ever dealt with the ADL complaints and charges?

A. I don't know what you mean by dealt with them. Whether—oh, go ahead.

Q. What my question has to do with is, do you know whether or not Dr. Deane or the NIH, which funded the Deane report, has made any attempt whatsoever to resolve this controversy?

A. I—I—I do know that there were discussions with general counsel about the requirement to respond to the objections of ADL in this report, and——

Q. Was that the matter having to do with——

A. Those were materials with which we were provided both by NIH and by the committee.

Q. Was that the matter having to do with the general counsel—was that the general counsel of the Department, or the Public Health Service?

A. I don't recall.

Q. It must have been either one, right?

A. It would have been either one. I don't recall which general counsel it was.

Mr. MICHIE. Do you know who that might have been, Mr. Riseberg? Was it your office?

Mr. RISEBERG. I can't help you.

By Mr. MICHIE.

Q. Was that matter involving Dr. Ketteringham's request at the end of his letter that this letter be appended to the report?

A. Yes.

Q. And did not the general counsel provide an opinion, in your recollection, provide an opinion to Dr. Deane or to someone at NIH stating that——

A. I believe——

Q. Because of the fact that ADL was a subcontractor to the National Nephrology Foundation that there was no need for the prime contractor to release that report to anyone? There was no obligation for them to show it to anyone, isn't that correct?

A. In substance, that was the opinion rendered.

Q. Did you, during the course of the assessment meet in your offices with Dr. Norman Deane?

A. Well, yes, we did as a matter of fact.

Q. When, and for what purpose did this meeting take place?

A. It was some time before June 25. I suspect it was June 18 or something like that. I think that was the right date.

Q. Did you discuss with Dr. Deane the charges made by his subcontractor, Arthur D. Little, that Deane had misrepresented the findings of Arthur D. Little in its vitro study of reused dialyzers?

A. I did.

Q. Was Dr. Deane able to refute the charges of Arthur D. Little?

A. No.

Q. None of the charges?

A. Well, the—he presented me with a document in which he had prepared rebuttals for the allegations outlined in this ADL comment, and the substantive point in question was whether or not there were data generated either by ADL or by National Kidney Foundation that would—that would tell you that reprocessing of a hollow fiber hemodialyzer, if done properly, and I am paraphrasing the particular statement or conclusion, would result in a hollow fiber hemodialyzer equivalent to a new one.

Well, there were no—Dr. Deane, at the time we met, admittedly—admitted basically that the numbers type data just didn't exist, and then we went on to discuss——

Q. The tables?

A. Pardon?

Q. The tables?

A. There were—which tables?

Q. The tables in his report?

A. Which tables do you refer to?

Q. In the Deane report. Did he not borrow some tables from the ADL report?

A. There are graphs.

Q. Graphs?

A. There were graphs in his report.

Q. And what did you discover about those graphs?

A. I don't know what—what you're referring to. I'm sorry.

Q. Had any changes been made in those graphs?

A. Between——

Q. Between the time they were taken from the ADL report and transposed into——

A. Oh, no, they were identical. You mean on the bacteriology of——

Q. On anything.

A. [Continuing.] On the bacteriology of organisms. No, there were no changes. They were redrawn, but they are the identical graphs.

I guess that was an issue in Dr. Deane's letter to me or at least in his comments at the time. We discussed whether ADL had done the work would support the claims made in this ADL communication, and Dr. Deane's position was that ADL didn't do such work, to which I took issue by showing him in the ADL report where the data was and were the same as he had presented.

Q. And so, to go back to your earlier answer, Dr. Deane was unable to refute the charges. Isn't that correct?

A. That's true.

Q. Now, here is an example on page 139 of Dr. Deane's report. Do you recall sitting here at your visit and my having shown this particular conclusion to you and then having presented you with the Lewis paper?

A. Yes.

Q. And what was your comment after looking at the Lewis paper, which had to do with anti and like antibodies and then looking at this comment. What was your response?

A. Well, apart from the citation, the comment was not what the Lewis paper concluded. The Lewis paper did not conclude that—that—would not be expected to produce any adverse effect and so forth.

It, in my recollection, and I don't have the Lewis paper available in front of me—if you do, I would like to have a copy of it to refresh my memory.

Q. But isn't it your recollection——

A. It is my recollection that the Lewis paper concluded quite the opposite, that there might be adverse effects. That they were not—that they weren't able to ascertain that there wouldn't be any adverse effects.

Q. And didn't you sit here on that morning after examining this statement in the Lewis paper and didn't you sit here and look up at me and say, "This is dishonest"? Didn't you say that?

A. I don't recall that.

Q. You don't recall?

A. I know that I was amazed by the transposition of the citation from a conclusion in a published paper into another published report with high degree of inaccuracy. It was wrong. I mean this is not what the Lewis paper concluded.

Q. But you are not suggesting that you have a definite recollection of having said, "This is dishonest." Is that correct?

A. I don't recall what I said then. To be honest with you, I just don't recall it. I just know at that time I was amazed, I was utterly amazed. It was the first time, actually, that I had had an opportunity—opportunity to critically look at certain elements of the Deane report, which were pointed out when we met here.

Q. What was Dr. Deane's comment at your meeting with him when you confronted him with this particular matter?

A. He had no comment.

Q. What do you mean by that?

A. He didn't say anything.

Q. He kept silent. Is that what you are saying?

A. Yes.

Q. Let me refer you now to page 6 of the assessment report what was forwarded to Dr. Windom on August 6. It is the second line from the top. Do you have that there, sir, the assessment report? It is page 6, second line from the top of the page.

Thank you. Quote: "Nephrologists have been persuaded by data of Deane" and there are two other names there, and it goes on to say, "and others, that reprocessed hemodialyzers maintain states of cleanliness, function and stability—high level infection—which is equivalent to the first use dialyzer."

My question for you, Dr. Carter, is, shouldn't this passage have begun by stating, "Although there is substantial controversy or serious question regarding the validity and integrity of the Deane report and its findings, nephrologists have been persuaded," et cetera.

Would that not have been more accurate and more informative?

A. I am sorry. I was reading here. You were saying? Could you repeat that?

Q. I am suggesting—let me read the question over again.

Shouldn't this passage have begun by stating, "Although there is substantial controversy or serious question regarding the validity and integrity of the Deane report and its findings, nephrologists have been persuaded," et cetera.

Wouldn't that have been more accurate and informative?

A. I think that more appropriate, in my view, would be that we would have probably included a critique of all the data we cite.

We are still trying to get our staff to do this in referencing material. It is just that sometimes there is so much material to review in a short time that it is not possible to accomplish——

Q. But especially in the case of this assessment, because you had to do this in less than a third of the time that you ordinarily would take on an assessment. Isn't that correct?

A. I——

Q. I mean you and Mr. Erlichman. The two of you were the only two people for all practical purposes who worked on this assessment. Isn't that right?

A. That is true.

Q. And in spite of that, you still managed to produce a document, one that perhaps does not contain everything that you want it to contain, but nonetheless, if you had been given more time in order to perform this assessment, past October 6, then you would have had the time to do all of this—this other work—insofar as referencing and appropriately qualifying statements such as this one.

Isn't that correct?

A. Well, when we edit these things, we do make—we clean up those areas, but I must say that—that I'm not totally happy with the way we have left this, without commenting on the qualitative aspects of the studies.

Q. I have here a copy of a February 19, 1986, note to Dr. Macdonald, the then Acting Assistant Secretary for Health. We are going to get that for you in just a moment.

A. Dated what?

Mr. **Riseberg**. He is going to get it to you.

Q. Dated February 19, 1986, and we will hand that to you now.

This note states that your agency, NCHSR, had, quote, down toward the bottom of the page, "Not been heavily involved in the dialyzer reuse issue." Was this a correct observation at that time?

A. On February 19, to my knowledge we hadn't been involved at all.

Q. Let's go on now to the public hearing on March 6 of this year conducted by this committee concerning the safety and efficacy of reuse.

A. I'm sorry.

Q. Go ahead.

A. The National Center for Health Care Technology, our predecessor organization, did have some involvement, to correct the record, but we, per se, had not not been involved. That goes back years ago.

Q. Years and years ago?

A. Yes.

Q. And at that time, was that particular assessment looking at reuse?

A. There wasn't an assessment. It was an ESRD coordinating committee that was one of the committees empowered by interagency collaboration to look at these issues.

Q. Fine; but no assessment?

A. No.

Q. As you recall, Dr. Marshall was the principal witness for PHS at the hearing, was he not?

A. Yes.

Q. I would like to share with you a copy of Dr. Marshall's statement for the record. And I think, as you testified earlier, you were involved in preparing his testimony?

A. That's correct.

Q. Was anyone else involved in that besides yourself and Dr. Marshall?

A. Yes.

Q. Who might that have been?

A. In the actual preparation, or——

Q. In the actual preparation.

A. I believe that I wrote the entire first draft of the testimony, and then we received input from FDA, NIH, review and input by CDC, and that's about it.

Q. You did, because of the—and correct me if I am wrong—but there weren't many days for you to prepare this testimony, were there?

A. There was not——

Q. I say that because Commissioner Young had been invited by the chairman of this committee and some time prior to the hearing date, as I understand it, and you correct me if I am wrong, Dr. Marshall was notified that he would be the witness, is that right?

A. I believe so. I was away when it all started, and I came back and we proceeded to start preparing testimony.

Q. When you did return; did you rely heavily on FDA for assistance in pulling this testimony together?

A. Well, in—in—so much as the sections that pertain to what the agencies are doing, we included information from those agencies.

Q. Let's move forward, now, in time to July 8, 1986.

Did you during the morning of July 8 meet with Dr. Marshall?

A. The morning of July 8?

Q. The morning of July 8, 1986.

This would have been on the same day of Dr. Marshall's meeting with Dr. Windom and others. Did you meet with him that morning?

A. I think so. I believe I did. I think I did. I met with him one morning, either that morning or the morning before.

Q. What was the purpose of this meeting?

A. Well, I think that at that time Dr. Marshall and I were discussing the assessment and the information that we were receiving, some of which was from agencies, from the committee, the outbreaks, the—the investigations that were underway, and I think that he wanted to follow up on some comments I had previously made to him about all these things.

Q. As a matter of fact, July 8, another deadline was upon you, wasn't it? Hadn't a new deadline of July 10 been set for the end of the assessment and a report? Do you recall that?

A. You see, believe it or not, I'm not sure about that, because I know that after June, if a deadline had been set after June, I don't know. The first time—the next deadline I know of was in August. But we just continued to work, and I don't recall that there was another deadline that I was made aware of as such.

Q. Do you recall, following your meeting with Dr. Marshall, Dr. Marshall drafting a memo for presentation to Dr. Windom at a meeting that afternoon? Do you recall that?

A. I believe so. I think that one of—some of—Dr. Marshall and I discussed some of the matters that he subsequently incorporated into a memorandum.

Q. And a number of these matters reflected you concerns, is that not correct, about the assessment, about the conduct of the assessment, about the direction it was taking, about the fact that you needed more time?

A. As a matter of fact, it was a joint concern.

I think Dr. Marshall was concerned, as I expressed to him some of the concerns of myself and our staff in terms of the rate at which we were discovering new things.

You must remember that that was 1 week following the MMWR report on the outbreaks, and the preceding week was a previous MMWR article, again, on—on formaldehyde, and there were developments that were cascading at a rate that indicated the need for more careful attention to the numerous developments.

Q. Let me share a copy of that July 8 memo with you, now.

A. I have read it so many times now, I suppose.

Q. Now, was this the memo that Dr. Marshall handed out at the meeting that afternoon, the afternoon of July 8 attended by Dr. Windom and others?

A. Yes.

Q. Did he hand out copies to everybody at the meeting?

A. You see, I don't know. I got there after the meeting had already started, Mr. Erlichman and I. And so everyone at—the meeting was probably 15 minutes or more in progress, so I don't know.

Q. The memo states, I think on the first page, "As events have unfolded, it is clear"—that is toward the bottom of the first paragraph—"it is clear that the March 6 testimony was not based on all the germane facts and that we may need to take a position counter to that which we argued on March 6. We need to ascertain a PHS position and inform HCFA of that position so as to minimize embarrassment for the Department."

Were these observations by Dr. Marshall based on information that you had provided to him when you met with him either that morning or the day before?

A. Well, I would have to say that I don't know which specific observations you refer to.

HCFA, I had not, believe me, I had not, I wasn't—I think for all the times I read this memo recently, I just don't—I have essentially blocked out most of what had to do with HCFA and their rates.

Q. Why is that?

A. Mainly because there are some interagency policy issues that, from my perspective, we do not seek to tell the other agencies what to do.

Q. But you can advise, can't you?

A. But the understanding is that since we do not have the oversight responsibilities over HCFA and other agencies, when they request our advice, we offer that advice, just as you would as a medical consultant to a primary care practitioner.

You would offer advice when requested and you don't go volunteering advice to tell people what to do. So we have not, I have not, this is in my view all along has been a reimbursement problem with HCFA, and I never understood it from the beginning, what the basis for it was. I don't understand it now, and I really hadn't tried to delve into it.

Q. You mean the reductions?

A. The reductions.

Q. Well, I mean, isn't it—isn't it reasonable for one to assume that the reason why they reduced the rates is because they wanted to reduce spending?

A. Possibly. I don't know. It is speculation, of course.

Q. Can you think of any other reason why you would have reduced the rates?

A. Well, if you think you are overpaying people, I think that would be, you know, one good reason, if——

Q. That's true. And then if you reduce rates, you save money, right? You save revenue?

A. Not always. Sometimes medical complications may eventuate adverse outcome.

Q. What did Dr. Marshall mean by events that unfolded that led him to conclude that it is clear the March 6 testimony was not based on all the germane facts? What did he mean by that, do you know?

A. I do not know. I cannot—believe me, I did not know this memo was being written, and I did not—we went to the meeting and I saw the memo there.

I didn't have a copy of it myself. I paid little attention to the memo at that time, because I was more interested in the discussion that was transpiring.

But I don't know—I don't know the specific data or information that he alludes to. I would just—I suppose I would have to speculate, and based on what I have told him and what he also knew.

As you know, about a month after this, we received an enormous amount of material from the committee, new information. We at that time were totally unaware of the outbreaks of bacteremia and sepsis, or even a putative death in Dallas—a death in fact; whether it is associated or not is unclear. We didn't know that in March. There were no outbreaks under investigation in March.

We hadn't seen any reports from any of the States, reuse studies, the tristate studies. We didn't know of EIR's, establishment investigation reports.

We didn't know of MDR's. I didn't know any existed. We didn't know at the time of the nature of the details to which Deane excepted—I mean ADL excepted in the Deane report. And I certainly was not aware of the things that were brought to my attention subsequently in terms—there is a wide range of specifics that I don't know.

Q. Fine. That's all right.

During the meetings with Dr. Windom and others on July 8, was the memo distributed, Dr. Marshall's memo—was there a discussion of this memo?

A. I think so.

You see, again, I got into the meeting at a time when most of the discussion had—had already progressed, and I got in there when it was almost ended.

Q. Nonetheless, while you were there, while you were present at that meeting, did anyone at any time while you were present criticize, admonish, reprimand, whatever term you want to use, Dr. Marshall in any way for having written his July 8 memo to Dr. Windom in the first place?

A. I don't know of any criticism or admonishment, or reprimand, I should say.

Q. Did anyone suggest to Dr. Marshall that he should not have written this memo in the first place?

A. You would have to ask Dr. Marshall. I would—you know, Dr. Marshall might be better able to answer that, because I——

Q. Well, do you recall anyone at that meeting asking Dr. Marshall to retrieve all copies of that memo?

A. I remember the meeting, at the meeting, the copies were collected, and they were all picked up at the meeting. So——

Q. And do you recall that person having told Dr. Marshall to dispose of all the copies?

A. I do remember at the end of the meeting someone suggested collecting the copies, and they were collected, and I believe—I don't recall—I believe that the suggestion that they be disposed of came up.

At that time, I was turning—I had turned—to somebody else, because the meeting was over, and was discussing something with them, about formaldehyde and parts per million, either with Dr. Favero or Marty Erlichman. And Dr. Favero and I had a discussion at the end of the meeting there about formaldehyde.

Q. Do—do you know if in fact Dr. Marshall picked up all the copies and disposed of them?

A. I assumed he did. I assumed he picked up the copies. I don't know what he did with them, whether they were disposed of, or not.

Q. Based upon your knowledge to date, Dr. Carter, as Director of OHTA and having closely supervised the development of the NCHSR assessment, do you think it would be wise at this time for anyone or anything, in light of the fact that there are no standards, nor are there completed guidelines for reprocessing, in light of the fact that whatever guidelines do exist only attempt to redress the reprocessing of the dialyzer;

In light of the fact that CDC's data base is unvalidated, in light of the fact that CDC's investigations show in all five clinics that they investigated that there are indeed serious problems with reprocessing procedures;

In light of the fact that in the State survey reports, especially in the District of Columbia and in the California reports, those reports indeed do confirm the findings of CDC about the problems that have led to injury, to hospitalization, and maybe even in one case, and maybe perhaps more, death of a patient;

In light of all the above, do you think it would be wise at this time for anyone, or anything, or any action to encourage increased reuse in dialysis clinics?

A. That's a big order there.

I can say this much: If by your question you mean that in light of our study and subsequent findings—our findings—by CDC and tristate studies, that uniform standards are not in place, if we—and correct me if I am not rephrasing your question correctly—that we would advise that some standards be brought about——

Q. No, no, no, that wasn't my question. That wasn't my question, Dr. Carter. My question was, in light of all these findings that have come to your attention——

A. Yes.

Q. Toward the end of your assessment and afterward, toward the end of your assessment and much of it afterward. As you know, you didn't receive that large stack of documents from CDC until August 11, much of which pertains to the very issues that I just elaborated on a moment ago in this question.

In light of all that, do you think it would be wise, as Director of OHTA and as a professional, do you think it would be wise at this time for anyone, or anything or any action to encourage increased reuse in dialysis clinics?

A. Our recommendations based on our findings and conclusions are spelled out in—in the—we develop recommendations that we submitted to the Public Health Service regarding what we believe are appropriate measures.

I think the report, in terms of the findings and conclusions, speaks to those areas in which we view that there either is a need for further action or that——

Q. But in the meantime, Dr. Carter, unless and until standards, or guidelines, or whatever you want to call them, are developed, and incidentally, FDA's estimate to the CBO on development of standards, enforceable standards, is 3 to 5 years.

In light of that, in light of the fact we haven't—still haven't—done the studies, regardless of what time studies you want to talk about, on mortality, morbidity, patient outcome. In light of all that, do you think it would be wise, and please try to give me a yes or no answer, it is a very simple question. Do you think it would be wise for anyone or anything or any action at this time to encourage increased reuse in dialysis clinics?

A. Well, I don't think that is a question that is amenable to a yes or no answer, and I will tell you——

Q. Why not?

A. Basically because if you look at the August 11 memorandum from Dr. Marshall to Dr. Windom transmitting the report, the second paragraph of that memorandum states fairly reasonably, I thought, that while reuse is not without hazard, and I think that is a correct statement, it has been established, established both during the course of these proceedings in terms of information you have presented and the responses that I have given, as well as through the numerous data that are available to look at, that there are hazards associated with reuse that have been identified. The magnitude of those hazards are not fully understood.

Q. True, and so——

A. And so it would be a fairly drastic response to these observations to terminate reuse at this time.

Q. I am not suggesting that, Dr. Carter. Please listen to my question.

A. While we are not in the possession of the full range of information.

Q. Dr. Carter, my question did not address terminating reuse. My question addressed simply, and I am going to read it a third time for you:

> In light of all the information you have now, do you think it would be wise for anyone, anything, or any action at this time unless and until you get the data you need, unless and until you have the standards or guidelines you need, to encourage increased reuse?

It is a very simple question, Dr. Carter. It has nothing to do with termination.

A. Well, I don't know that—I don't know—again, I don't know that there is reason to encourage or discourage reuse.

Q. I didn't ask you that. I didn't ask you that.

A. I think that what there are reasons to—to—to do is to generate further data on the scope of the problems that have been identified, and also to understand them better and to find additional guidelines that would enable people who choose to reuse to do it safely and effectively.

Q. All right.

Dr. Carter, I didn't ask you to determine whether or not anything at all was going to encourage or discourage. My question is, in light of all the information you have now, and in light of the paucity of data with regard to safety of reuse, do you think it would be wise for anyone, anything, or any action at this time to encourage increased reuse? Yes or no.

A. Well, I still have to go back to the points that I have started out to make, which is that problems have been identified, and I believe that we need to systematically look at them.

Q. And resolve them?

A. Better—first better understand them and clearly resolve them.

Q. And in the meantime, what do the patients do?

A. I believe that——

Q. Do they hope for the best. Is that what you are suggesting?

A. I am not suggesting that the patients cross their fingers.

I am suggesting that information, appropriate information, be provided to patients regarding what is known or not known about the practice, and provisions are made in 45 CFR for that particular—for informed consent.

And the California guidelines provide for mandatory informed consent. I think that that's an appropriate response, accompanied by, perhaps, individual choice given that information. Freedom of choice would be worthless in the absence of—I am sorry—informed consent would be worthless in the absence of freedom of choice.

So that I, you know, I don't think we are talking about encouraging or discouraging anything. I think we are talking about responsible measures to—to—to——

Q. I am not suggesting, Dr. Carter, that you want to discourage or encourage anything. I am asking you a very simple direct question. I am going to ask you the fourth time, and I would please ask you to answer the question if you can.

Bearing in mind all the information you have collected, all the information that you know now with regard to the absence of data, the paucity of data, the lack of standards, lack of knowledge, the lack of an adequate data base. Bearing all that in mind, do you think that unless and until all these things are resolved that it would be wise for anything, anyone, or any activity or action to encourage increased reuse?

A. I think it would be wise for us to step up our surveillance——

Q. But what about——

A. To understand better if there is a big problem, because we could be doing—you see, when you take sampling, if you take an outbreak, that is by definition, I mean you are going to the problem, that—a problem—but we don't know, you know. There is such a thing as bias sampling, by definition, that you only go where the problems are, and we're talking about sampling by—I can say this——

Q. Dr. Marshall, I have asked you this question——

Mr. Riseberg. Dr. Carter.

Q. I am sorry. Dr. Carter, I have asked you the question four times. Now, if you're declining to answer the question, please state so for the record.

A. No; I am trying to be precise, in what I consider to be a responsible and correct answer, which is that I—I don't think we—I think that our assessment has given us the kind of information which tells us what questions needed to be asked, or answered.

And so starting with that, I think that we are now in a position to say that I would like to know how—whether or not—the District of Columbia findings are representative of other facilities, or just the District of Columbia, and I would like to know what the California report means by "out of control reuse practices" means. I, you know——

Q. Dr. Carter, I understand. I think we all want to know all that.

But I still ask you, will you please answer the question that I have asked you four times before?

In light of what you know now, do you believe it would be wise at this time for anyone, anything, or any action to encourage increased reuse in dialysis clinics?

Yes or no, please.

A. I really don't have sufficient—what I am saying is that I don't have sufficient information to answer that, because we would not know until we—the responsible thing would be to find out first what the scope of the problem is before we put up the red flag and say "Stop."

Q. Dr. Carter didn't you once state to me in the recent past that right now there is no way for you to know how many patients are dying out there——

A. Well, yes, you asked a question in response to the dialysis issue on that particular death, and we have no idea. We don't know if that is an isolated occurrence or whether there are additional occurrences, but—I have no idea.

Q. Wouldn't it be the prudent thing and the ethical thing for the medical community to err on the side of caution?

A. I think it is always prudent, as in my medical training, primo non nastere was the guiding beacon we functioned by, "First do no harm."

And yes, you must always err on the side of caution in proceeding and managing patients.

What I am saying is that, right now, despite 80,000 patients being dialyzed of which maybe close to 40,000 are on reuse treatments, per year, 40,000 patients per year constituting, just imagine the multiplier, 365—I am sorry, 52 weeks like 350 treatments per patient times 40,000—that's an enormous number of treatments. I don't know what the data suggest regarding complications.

Q. Well, of course not, and doesn't that disturb you?

A. There are enormous numbers of patients and opportunities. My—my—my desire is know, and it is not to form conclusions prematurely.

Q. Doesn't the sheer fact that you don't know, doesn't that concern you?

A. Why, certainly.

Q. What does the patient do in the meantime, Dr. Carter? Does he hope for the best?

A. Well, I—I believe that in almost any procedure performed, or treatment performed on a patient, there is informed consent.

Q. I have one last question, Dr. Carter, because I understand you have to leave here at 12:30.

In your honest opinion, as you sit here today as a physician, as head of OHTA, the office responsible for conducting assessments with regard to health care technology, do you believe, or do you not believe, that it would be wise and prudent in the interests of this Nation's 80,000 dialysis patients for HCFA to withdraw the dialysis rate reductions while NCHSR is given sufficient, adequate time to complete a thorough assessment of this very complicated issue of reuse? In the interests of the patient, of course.

A. I must say this much. I have no idea what the answer to that should be. I really don't.

And it's largely, in part, due to the fact that the assumption that we use per se is generating increased—I am sorry, rate reductions per se—are generating increased reuse behavior is primarily an assumption.

I have no idea what kind of profits are going into the—into those—centers or losses, or costs. We have some rudimentary cost information, but I don't know what kinds of margins these people are talking about, and whether or not there is waste, whether fraud, abuse, overcharging, undercharging.

I really don't know that, and while I do know that some have commented suggesting that reductions in rates will increase their reuse, as I indicated, we don't know that reuse alone, per se, is the problem. Maybe it is whether you do it right or wrong.

And so I would prefer to address the particular problem. I would like to know what the problem is in the first place. Is it reuse per se, or are they doing it wrong?

Q. In the meantime, Dr. Marshall, what does the patient do? What does the patient do, Dr. Carter?

We have seen many, many examples in the State surveys and also in the investigations of the CDC.

We have seen many example of life-threatening, injury-threatening, inadequate procedures. As a matter of fact, in one clinic in Georgia, as you may have read in the material that you received belatedly from CDC. that clinic didn't even have a procedure for reprocessing its writing. Do you recall that?

A. Yes.

Q. Now, my question to you again is, while it takes you 3 years, maybe 5, to come to some understanding, to have some definitive answer on how many patients are dying every year of infection and other causes, because to reuse, perhaps, what do the patients do in the meantime, Dr. Carter?

A. I must say that I am not——

Q. Have you given any thought to that?

A. Oh, yes, I have given a significant amount of thought to it.

Q. Well, what advice do you have for the dialysis patient who does not want to reuse but has no alternative because the clinic forces reuse upon him?

What does the patient do in the meantime, Dr. Carter, while everyone continues to gather data, or whatever, to have a certain answer about what's out there?

A. I must say that we really have not focused in on——

Q. On the patient?

A. No; on the whole area, with any great amount of emphasis on how best to explore options for that area of informed consent and freedom of choice.

We have looked at what exists so far, and believe that there is a range of informed consent being provided, and I—I like the California informed consent guidelines, because I think that they represent the reasonable level of care and attention.

But I don't know, I don't know. I don't know, other than to say that in other areas of medicine patients rely on informed professional opinion, and information.

Q. And isn't that the case with the patients who were hospitalized in the clinics that were investigated by CDC? Didn't they rely upon the professional prowess of the clinicians in those clinics, and what happend to those patients? They went to the hospital, didn't they? So what does that prove, Dr. Carter?

A. Well, to me it doesn't prove anything other than to say that there are practitioners whose level of skill, expertise, and competence requires more careful surveillance through peer review or other mechanisms.

But I don't—I don't—in this—I assume you are referring to the Louisiana outbreaks.

Q. No; I am referring to the outbreaks this year. There were patients hospitalized in those outbreaks. Were you not aware of that?

A. I am aware of that.

All I can say that mechanisms should exist by which to ensure that the optimal safety of the patient is safeguarded.

Q. But they don't, Dr. Carter, and my question again is, what does the patient do in the meantime?

A. I can't answer that to the extent that I am not prepared to address the alternative mechanisms for providing patients that option.

Mr. MICHIE. Thank you, Dr. Carter. Thank you very much.

I want to remind you that you are subject to recall for testimony in this deposition. The transcript of this deposition will be sealed, a copy of which will be sent to you for correction.

In the meantime, this deposition is recessed.

Thank you, gentlemen.

JOHN HEINZ, PENNSYLVANIA, CHAIRMAN

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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510

August 28, 1986

Mr. Richard J. Riseberg
Chief Counsel
U.S. Public Health Service
U.S. Department of Health and
  Human Services
Parklawn Building, Room 4A53
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Rockville, Md. 20857

Dear Mr. Riseberg:

I have reviewed transcripts of the appearance of your clients, Drs. John E. Marshall and Enrique D. Carter and Mr. Martin N. Erlichman, at depositions of the Special Committee on Aging on August 22 and August 26, 1986. I have noted your clients' refusals to take the oath that Committee Rule 6.3 provides for the court reporter/notary public to administer at the outset of a deposition.

Based on the remarks of your clients and yourself at these depositions, I understand your clients to have raised two objections. First, you have questioned the legitimacy of the Committee's issuance of subpoenas directing witnesses to be examined by Committee staff at deposition, without the presence of Members of the Committee. Second, you have questioned the authority for an oath to be administered at a Committee deposition by anyone who is not a Member of Congress.

I request that you communicate to your clients that, upon consideration of these two objections, as Chairman of the Committee, I have overruled both objections. First, section 104(c)(1) of Senate Resolution 4 explicitly authorizes the Committee to require the attendance of witnesses by subpoena and to take depositions. Your apparent contention that the deposition authority does not authorize depositions by Committee staff is incorrect. The word "deposition," in contrast to the word "hearing," refers to examination by staff only. This interpretation of the word "deposition" is the only interpretation that is consistent with well-established congressional practice as well as the common meaning of the word in extra-congressional legal contexts. I rule that the Senate has authorized the Committee to subpoena witnesses to testify at depositions conducted by Committee staff.

Second, Committee Rule 6.3, which provides for the administration of oaths at staff depositions by "an individual authorized by local law to administer oaths," is consistent

with governing legal authority. Your contention that section 104(c)(2) of Senate Resolution 4, which authorizes the Chairman or any Member of the Committee to administer oaths, precludes a notary public from administering an oath at deposition is incorrect. Section 2903(c) of title 5 of the U.S. Code, in concert with section 104(c)(1)(G) of Senate Resolution 4, pursuant to the Senate's constitutional rule-making power, authorizes administration of oaths to witnesses at Committee staff depositions by individuals authorized by local law to administer oaths. Accordingly, I rule that your clients are required to take an oath to be administered by any individual designated by the Committee staff who is authorized to administer oaths by local law.

I would appreciate your advising each of your clients who has refused to be examined by Committee staff at deposition under an oath to be administered by a notary public of my rulings on their objections. If Drs. Marshall and Carter and Mr. Erlichman remain unwilling to comply with the requirements of the subpoenas with which they have been served, subpoenas may be issued compelling their attendance at a hearing of the Committee in order for them to show cause why they should not be held in contempt of Congress. Please advise Mr. James F. Michie, Chief Investigator for the Special Committee on Aging, and Mr. Morgan Frankel of the Office of Senate Legal Counsel, of your clients' intentions.

Sincerely,

John Heinz

JOHN HEINZ
Chairman

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